

EXHIBIT L

US005810872A

United States Patent [19][11] **Patent Number:** **5,810,872****Kanesaka et al.**[45] **Date of Patent:** **Sep. 22, 1998**[54] **FLEXIBLE STENT****FOREIGN PATENT DOCUMENTS**

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[57] **ABSTRACT**[21] **Appl. No.:** **819,566**

An expandable tubular reinforcing member of the invention is used for a body lumen, such as a blood vessel for reinforcement. The reinforcing member is formed of a tortuous section having a plurality of laterally extending elongated members, and a plurality of vertically extending end members situated between two adjacent elongated members for connecting the same. The tortuous section is arranged diagonally to form a cylindrical shape with a first diameter extending in a spiral form. The elongated members generally extend parallel to a central axis of the cylindrical shape. A plurality of joint members is situated between two end members arranged in the cylindrical shape to keep the shape. When a radial force is applied from an inside of the reinforcing member, the elongated members are bent relative to the end members to thereby allow the tubular reinforcing member to have a second diameter larger than the first diameter to thereby hold the body lumen.

[22] **Filed:** **Mar. 14, 1997**[51] **Int. Cl.⁶** **A61M 25/00**[52] **U.S. Cl.** **606/198; 623/1; 623/12**

[58] **Field of Search** 606/1, 108, 191,
606/194, 195, 198, 200; 623/1, 12

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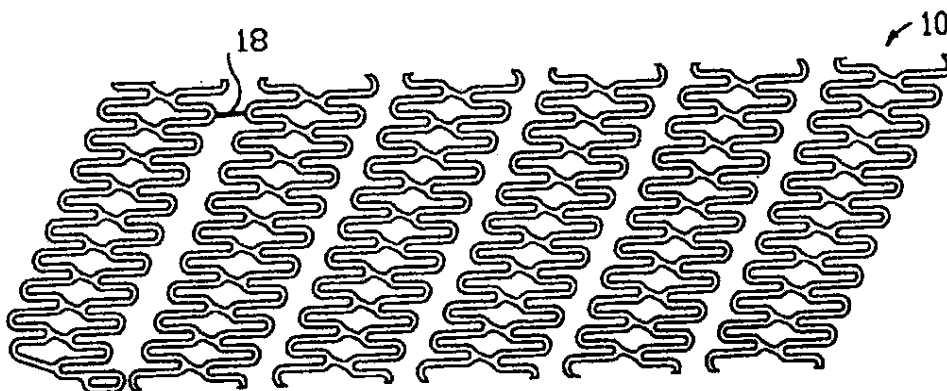
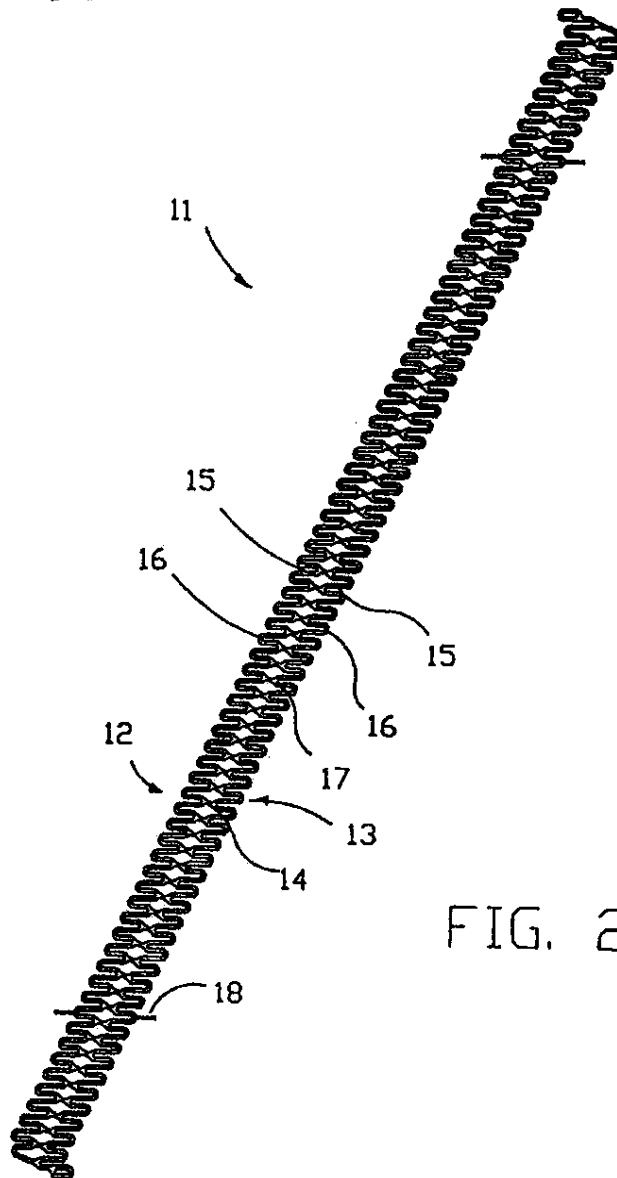
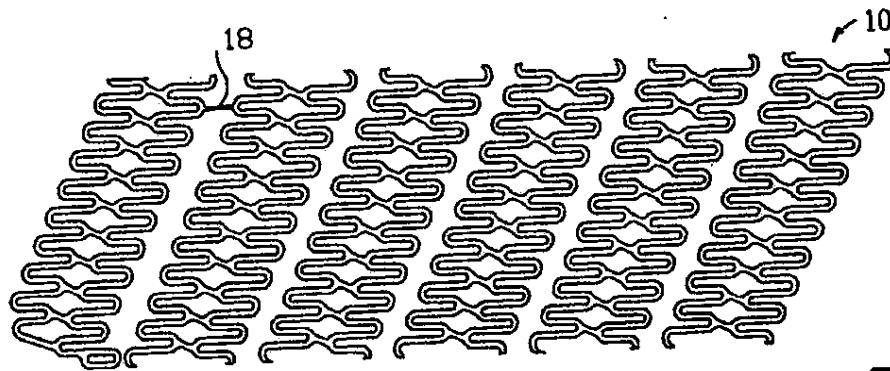
15 Claims, 5 Drawing Sheets

FIG. 1



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FIG. 3

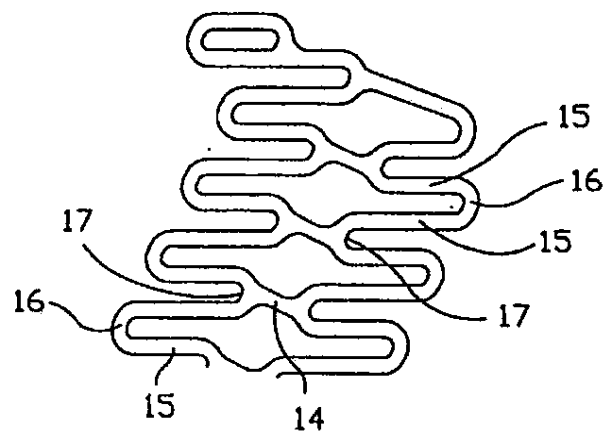
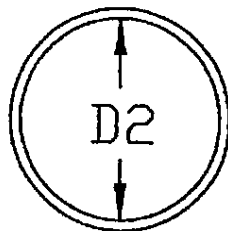
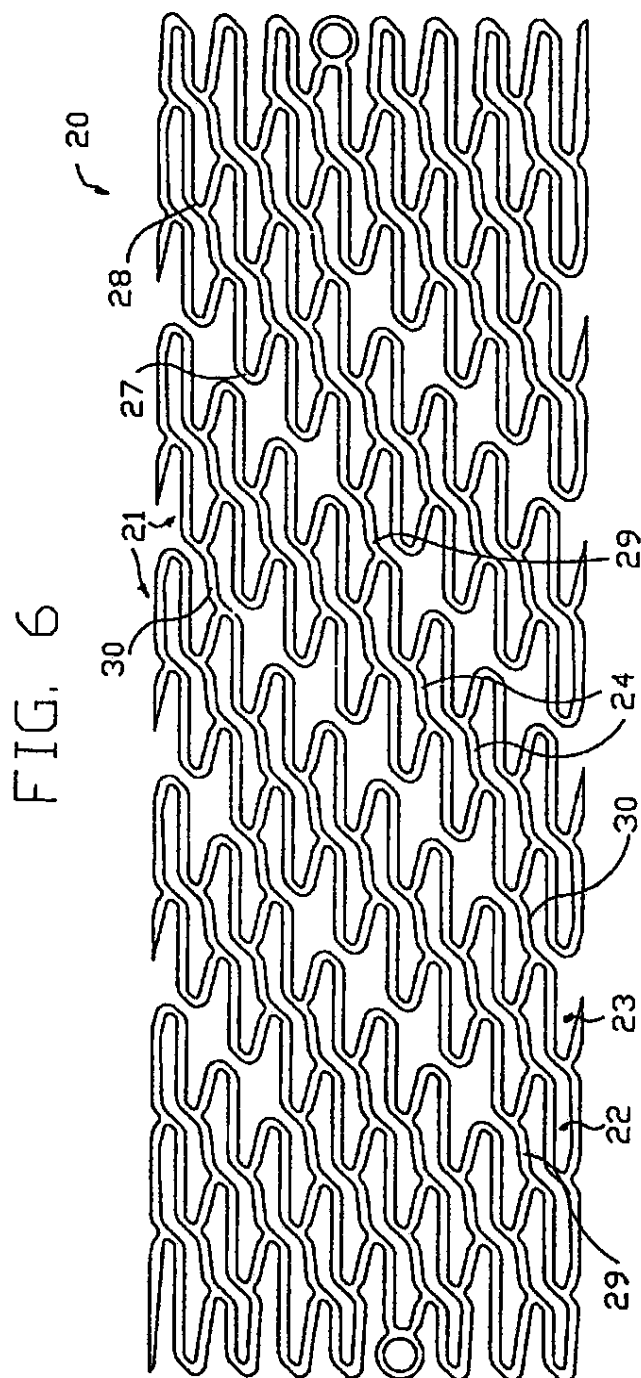


FIG. 4



FIG. 5





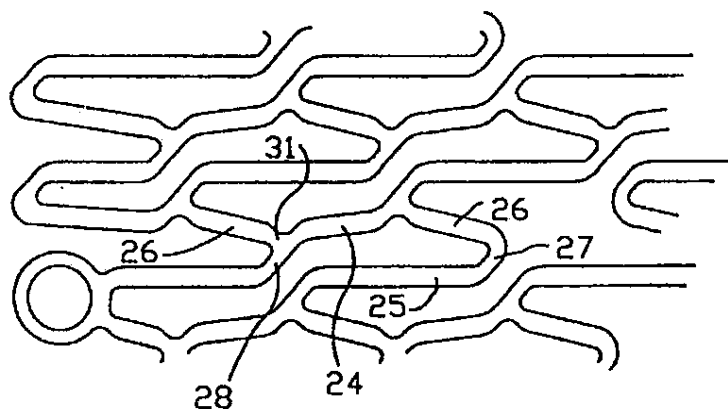
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FIG. 7

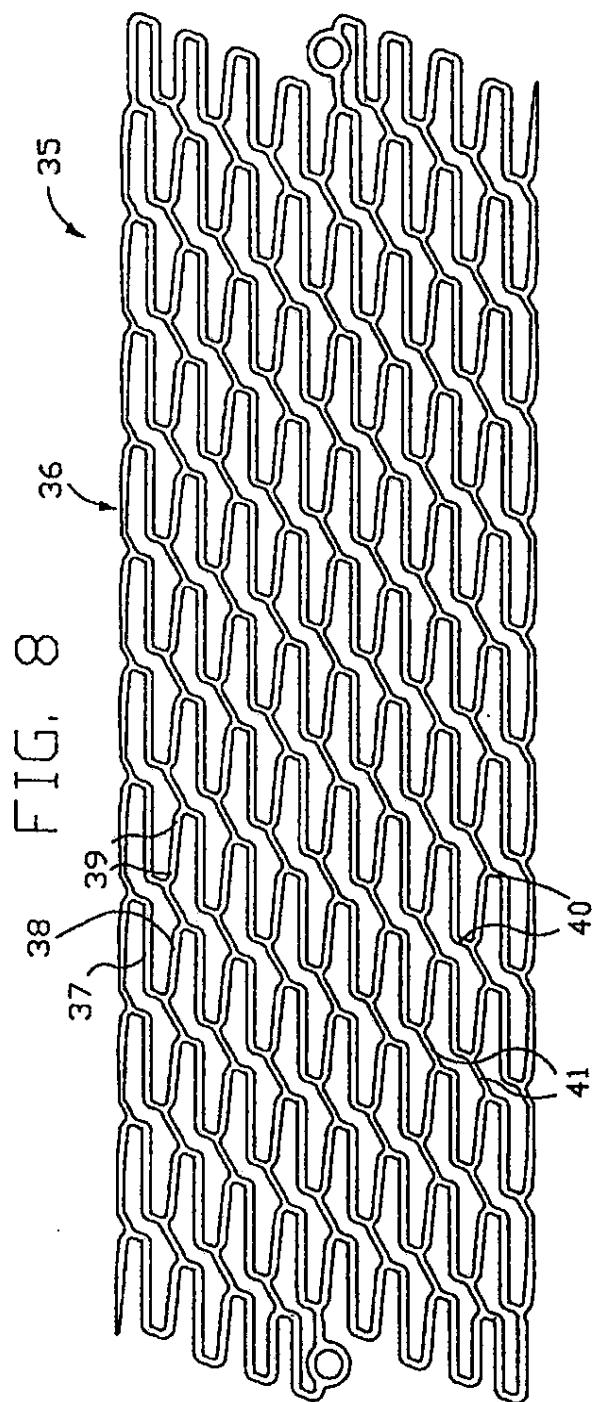


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FLEXIBLE STENT

BACKGROUND OF THE INVENTION AND
RELATED ART STATEMENT

The invention relates to a flexible stent to be implanted within body lumen, such as an artery, to maintain patency thereof. "Stent" here is defined as a prosthetic member used for reinforcing the blood vessel, and is very useful in the treatment of atherosclerotic stenosis in blood vessels.

When the body lumen is weakened, for example, dissectional artery lining occurs in a body lumen such as a blood vessel, the weak part of the body lumen might collapse to occlude a fluid passageway. To prevent such an occlusion, a stent is implanted within the blood vessel to support the blood vessel from the inside thereof. Namely, a stent is delivered to a desired location in the blood vessel, and expanded in a circumferential direction in the blood vessel to support and maintain the patency of the blood vessel. Using the stent to support the blood vessel can avoid surgical exposing, incising, removing, replacing or bypassing a defective blood vessel required in the conventional vascular surgery.

There have been introduced various types of stents, and they can be typically categorized from viewpoints of methods for expanding the stent, shapes, methods for manufacturing the stent, designs and so on. From a viewpoint of methods for expanding the stent, stents can be categorized as a self-expandable stent which can be expanded by itself, and a balloon expandable stent. In the balloon expandable stent, the stent is mounted on an expandable member, such as a balloon, provided on a distal end of an intravascular catheter, and the catheter is advanced to the desired location in the body lumen to deliver the stent. Then, the balloon on the catheter is inflated to expand the stent into a permanent expanded condition, and the balloon is deflated for removing the catheter from the stent.

From a viewpoint of materials, stents can be categorized into a tubular stent and a wire stent, and from a viewpoint of methods for manufacturing the stent, stents can be categorized as an etched stent and a laser cut stent. Then, from a viewpoint of designs, stents can be categorized into numerous types, but roughly, stents can be categorized into a stent having a zigzag pattern on the surface thereof, and a stent having a diamond pattern on the surface thereof.

Further details of prior art stents can be found in U.S. Pat. No. 5,562,697, U.S. Pat. No. 5,540,713, U.S. Pat. No. 5,575,816, U.S. Pat. No. 5,569,295, U.S. Pat. No. 5,496,365, U.S. Pat. No. 5,344,426, U.S. Pat. No. 5,139,480 and U.S. Pat. No. 5,135,536.

In all types of stents, the stent expands from an initial diameter to a larger diameter so as to be suitable for a particular size of the targeted body cavity. Therefore, the stent must have expandability in the circumferential direction. Also, since the reason why the stent is placed in the body lumen is to support a cavity wall therein to maintain the patency thereof, it is very important that the stent has radial strength as well as support capability.

At the same time, since the stent is generally delivered through tortuous path to the desired location in the body lumen, the stent must have flexibility in the axial direction. Namely, the stent must be flexible and is bent easily to thereby facilitate the delivery of the stent in the narrow and meandering body lumen.

In the aforementioned various types, since a wire stent is made by simply bending a wire having flexibility, the wire

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stent is not only expanded easily, but also shrunk easily. Namely, the wire stent does not have support capability for maintaining the expanded condition in order to keep the body lumen open. On the other hand, a tube type stent has enough support capability to maintain its expanded condition for holding the body lumen open. However, since the tube stent is not flexible in the axial direction, it is difficult to deliver the tube stent in the tortuous lumen to locate the stent in the desirable site.

In the zigzag pattern stent, struts attached in zigzag shape are connected in the circumferential direction to form a tubular shape stent. Therefore, when the stent is expanded, the zigzag shaped struts expand in the circumferential direction, but easily pushed back. Although the zigzag pattern stent has flexibility in the axial direction to facilitate the delivery of the stent in the body lumen, the zigzag pattern stent does not have enough radial strength and support capability to support the body lumen and maintain the patency thereof.

In the stent having a diamond pattern, struts forming diamond shapes are connected in the circumferential direction to form a tubular shape stent. As the diamond pattern stent opens, the diamond shapes expand to give scuffling structure to the stent for excellent radial strength to maintain the patency of the body lumen. The diamond pattern stent, however, has almost no flexibility in the axial direction.

In order to improve axial flexibility in the diamond pattern stent, many attempts have been made by placing flexible curved joints between diamonds, or by removing some joints between diamonds which are connected in the axial direction. These attempts did contributed to improvement for the axial flexibility of the diamond pattern stent in a certain degree, but did not fully improve axial flexibility to be comparable level of the zigzag pattern stent.

Accordingly, an object of the invention is to provide a stent, which has a high degree of flexibility in the axial direction to advance through narrow tortuous passageways.

Another object of the invention is to provide a stent as stated above, which also has strong radial strength and support capability in the circumferential direction.

Further objects and advantages of the invention will be apparent from the following description of the invention.

SUMMARY OF THE INVENTION

To achieve the aforementioned objects of the invention, a stent or an expandable tubular reinforcing member is formed of a tortuous section having a plurality of laterally extending elongated members, and a plurality of vertically extending end members situated between two adjacent elongated members for connecting the same. The tortuous section is arranged diagonally to form a cylindrical shape with a first diameter extending in a spiral form so that the elongated members generally extend parallel to a central axis of the cylindrical shape. A plurality of joint members extends between two end members arranged in the cylindrical shape and situated adjacent to each other. When a radial force is applied from an inside of the reinforcing member, the elongated members are bent relative to the end members to thereby allow the tubular reinforcing member to have a second diameter larger than the first diameter.

In the invention, since the tortuous section is arranged spirally, the stent can be bent easily along the longitudinal direction thereof to thereby facilitate insertion of the stent to a desired portion in the blood vessel.

The tortuous section may be formed of a first tortuous member having a plurality of first lateral members, and a

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plurality of first vertical members situated between two adjacent first lateral members for connecting the same, the first tortuous member extending continuously from an end to an end; a second tortuous member having a plurality of second lateral members, and a plurality of second vertical members situated between two adjacent second lateral members for connecting the same, the second tortuous member extending continuously from an end to an end; and a plurality of connecting members. Each connecting member is situated between the first and second vertical members to connect the first and second tortuous members together as one unit. The connecting members are arranged diagonally along the periphery of the cylindrical shape in the direction of expansion from the first diameter to the second diameter.

Since the tortuous section is formed of the first and second tortuous members connected by the connecting members, the stent can possess sufficient rigidity as well as longitudinal flexibility.

The elongated members may include long members and short members arranged one after the other. Each short member has inclined ends connected to the end members, and each end of the joint member is connected to both the inclined end and the end member.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a stent extended in a flat form according to a first embodiment of the invention;

FIG. 2 is a plan view of a strip forming the stent as shown in FIG. 1;

FIG. 3 is an enlarged plan view of a part of the strip shown in FIG. 2;

FIG. 4 is a front view of the stent before it is expanded;

FIG. 5 is a front view of the stent after it is expanded;

FIG. 6 is a side view of a stent extended in a flat form according to a second embodiment of the invention, wherein two strips are wound to form the cylindrical shape stent;

FIG. 7 is an enlarged plan view of a part of the strip forming the stent shown in FIG. 6;

FIG. 8 is a side view of a stent extended in a flat form according to a third embodiment of the invention, which is formed of a plurality of tortuous members.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENTS

Hereinafter, an embodiment of the present invention is explained with reference to the attached drawings.

A stent 10 of a first embodiment of the invention is shown in FIG. 1. The stent 10 is formed of a diagonally arranged strip 11 as shown in FIG. 2, which is wound spirally in a cylindrical shape. The strip 11 includes two tortuous members 12, 13 connected by connecting members or joint struts 14. As shown in FIG. 3, each of the tortuous members 12, 13 is formed of a plurality of parallel members or struts 15 and convex portions 16, 17 for connecting the struts 15. Thus, each tortuous member extends continuously and diagonally in a waving form. The tortuous members 12, 13 are connected by the connecting members 14 at the convex portions 17. The connecting members 14 extend diagonally, so that when the stent 10 is enlarged, the connecting members 14 can be bent easily.

In the embodiment, the strip 11 is formed from a flat metal sheet by etching process or laser cutting. However, it is possible to form the pattern in a metal tube by etching.

Then, in the embodiment of the present invention, the strip 11 is wound spirally in a circular shape, and the wound

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strip in the circular shape is partly connected by bridge struts 18 to prevent unwinding. The bridge strut 18 should be formed at both ends in the circular shape to keep the shape at the ends, but one or more bridge strut 18 may be formed in the middle portion thereof. No bridge strut 18 may be formed in the middle portion.

In this structure, the stent 10 is formed by simply winding the strip 11 spirally into a circular shape, wherein the portions of the strip 11 situated adjacent to each other are only partly connected together. Therefore, the stent in the circular shape can be easily bent along the axial direction at portions between the adjacent portions. Accordingly, the stent 10 has high flexibility in the axial direction to easily deliver the stent in the tortuous passageway such as body lumens.

In the strip 11 of the invention, the convex portions 17 are connected by the joint strut 14. As compared to a diamond pattern stent in which ends of struts forming one diamond shape are connected to ends of struts forming another diamond shape, the structure of the invention in which the joint strut 14 is connected to the convex portions 17 gives higher stability.

When the above constructed stent 10 is implanted in a body lumen, such as an artery, firstly, the stent 10 having an initial diameter D_1 (FIG. 4) is delivered into the artery to be located in the desired location. While the stent 10 is delivered in the meandering artery, the stent can be bent easily because of the spiral structure. Then, the stent 10 is expanded to have a second diameter D_2 as shown in FIG. 5, which is larger than the initial diameter D_1 and is located at the artery wherein the implantation of the stent is necessary. When the stent 10 is expanded to open the passageway in the artery, the parallel struts 15 are inclined at the convex portions 16, 17. Namely, the convex portions 16, 17 are bent, like opening a mouth. The expanded stent 10 has a scuffling structure to have enough stability and strength to prevent the stent 10 from shrinking, so that the artery can be remained open.

Incidentally, when the stent 10 is delivered and expanded, a delivery catheter assembly with an expandable member, such as a balloon, can be used. When the catheter assembly with a balloon is used to deliver the stent 10, the stent 10 is mounted on the balloon, and catheter assembly is pushed into the implantation site. Then, the balloon is inflated for radially applying the force inside the stent 10, and the stent 10 is expanded to have the second diameter D_2 .

preferably, when the stent 10 is constructed, end portions of the strip are adjusted in lengths, so that the ends of the stent 10 can be straight.

FIGS. 6 and 7 show a second embodiment 20 of a stent of the invention, which is formed by spirally winding two strips 21 situated adjacent to each other. The strip 21 includes two tortuous members 22, 23 connected by connecting members or joint struts 24. As shown in FIG. 7, each of the tortuous members 22, 23 is formed of a plurality of struts 25, 26 and convex or connecting portions 27, 28 for connecting the struts 25, 26. The struts 25 extend substantially parallel to the central axis of the stent 20, but the struts 26 slightly incline in the expanding direction. The struts 25, 26 may slightly incline in a vertical direction relative to the central axis. Each tortuous member extends continuously and diagonally in a waving form. The tortuous members 22, 23 are connected by the diagonal connecting members 24 at the convex portions 28.

In the embodiment 20, two strips 21 are jointed by joining members 29 and are wound spirally in a circular shape, and

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the wound strips in the circular shape are partly connected by bridge struts 30 to prevent unwinding. The jointed members 29 and the bridge struts 30 may be straight or curved.

As shown in an enlarged view of a part of the strips 22 of FIG. 7, each portion 31 at which the strut 26 is connected to the convex portion 28 has a size smaller than that of a middle portion thereof. Also, end portions of the joint strut 24 have a size smaller than that of the middle portion thereof. Therefore, when the stent 20 is opened, the struts 24, 26 can be bent easily. In the stent 20, when it is expanded, the connecting portions 27, 28 do not change the positions, and the struts 24, 25, 26 are bent relative to the connecting portions 27, 28. The stent 20 operates as in the stent 10.

FIG. 8 shows a third embodiment 35 of the stent of the invention. The stent 35 is formed of a plurality of tortuous members 36 spirally arranged in a cylindrical form. The tortuous member 36 includes long struts 37, and short struts 38 with inclined portions 39 at both ends. Connecting portions 40 connect the short and long struts 37, 38 to form the tortuous member 36. The tortuous members 36 situated adjacent to each other are connected by joint struts 41. The stent 35 can be used as in the first and second embodiments.

When a stent is expanded, in general, force is applied to the ends of the stent. In order to open the stent 35 easily and equally throughout the entire length thereof, the size of the end portions 39 of the strut 38 is made small. Alternatively, end portions of the strut 41 can be set to have a smaller size than those of struts and the middle portion of the strut. Accordingly, when the stent is expanded, the strut 41 can be bent at the ends with the smaller size so as to avoid warping.

In the present invention, since the tortuous member is arranged spirally, the stent can be bent in the longitudinal direction relatively easily when the stent is placed in a patient body. Also, the stent of the invention can be opened easily and holds the pressure applied thereto after it is expanded.

While the invention has been explained with reference to the specific embodiments of the invention, the explanation is illustrative and the invention is limited only by the appended claims.

What is claimed is:

1. An expandable tubular reinforcing member used for a body lumen comprising,
 - a tortuous section having a plurality of laterally extending elongated members formed of one kind of long members and one kind of short members arranged one after the other, and a plurality of vertically extending end members situated between two adjacent elongated members for connecting the same, said tortuous section being arranged diagonally to form a cylindrical shape with a first diameter and extending in a spiral form so that the elongated members generally extend along a central axis of the cylindrical shape, and
 - a plurality of joint members extending between two end members arranged in the cylindrical shape and situated adjacent to each other so that when a radial force is applied from an inside of the reinforcing member, the elongated members are bent relative to the end members to thereby allow the tubular reinforcing member to have a second diameter larger than the first diameter.
2. An expandable tubular reinforcing member used for a body lumen comprising,
 - a tortuous section having a plurality of laterally extending elongated members, and a plurality of vertically extending end members situated between two adjacent

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elongated members for connecting the same, said tortuous section being arranged diagonally to form a cylindrical shape with a first diameter extending in a spiral form so that the elongated members generally extend along a central axis of the cylindrical shape, and a plurality of joint members extending between two end members arranged in the cylindrical shape and situated adjacent to each other so that when a radial force is applied from an inside of the reinforcing member, the elongated members are bent relative to the end members to thereby allow the tubular reinforcing member to have a second diameter larger than the first diameter, wherein said tortuous section includes:

- a first tortuous member having a plurality of first lateral members, and a plurality of first vertical members situated between two adjacent first lateral members for connecting the same, said first tortuous member extending continuously from an end to an end,
 - a second tortuous member having a plurality of second lateral members, and a plurality of second vertical members situated between two adjacent second lateral members for connecting the same, said second tortuous member extending continuously from an end to an end, said first and second lateral members constituting the elongated members and said first and second vertical members constituting the end members, and
 - a plurality of connecting members, each being situated between the first and second vertical members to connect the first and second tortuous members together as one unit, said connecting members being arranged diagonally along the periphery of the cylindrical shape in the direction of expansion from the first diameter to the second diameter.
3. An expandable tubular reinforcing member according to claim 2, wherein said first lateral members are arranged parallel to each other; each of the first vertical members is curved to protrude outwardly relative to the first lateral members; the second lateral members are arranged parallel to each other; and each of the second vertical members is curved to protrude outwardly relative to the second lateral members.
 4. An expandable tubular reinforcing member according to claim 3, wherein said joint members are formed to connect some of the first and second vertical members.
 5. An expandable tubular reinforcing member according to claim 2, wherein said first lateral members include long members and short members arranged one after the other, said short members inclining slightly toward a bending direction thereof; and said second lateral members include long members and short members arranged one after the other, said short members inclining slightly toward a bending direction thereof.
 6. An expandable tubular reinforcing member according to claim 5, wherein said long and short members of the first and second lateral members have sectional dimensions smaller at end portions than at middle portions to facilitate bending of the long and short members.
 7. An expandable tubular reinforcing member according to claim 6, wherein said joint members extend diagonally along the periphery of the cylindrical shape in the direction of expansion from the first diameter to the second diameter.
 8. An expandable tubular reinforcing member according to claim 2, wherein a plurality of said unit, each being formed of the first and second tortuous members and the connecting members, is arranged side by side and wound in the spiral form.

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9. An expandable tubular reinforcing member according to claim 1, wherein each short member has inclined ends connected to the end member, each end of said joint member being connected to both of the inclined end and the end member.

10. An expandable tubular reinforcing member according to claim 1, wherein one of two kinds of the long and short members extends parallel to the central axis of the cylindrical shape, and the other of the two kinds of the long and short members inclines relative to said one kind in a direction of expansion from the first diameter to the second diameter.

11. An expandable tubular reinforcing member according to claim 10, wherein said long members extend parallel to the central axis, and the short members incline relative to the long members.

12. An expandable tubular reinforcing member used for a body lumen comprising,

a tortuous section including a plurality of laterally extending elongated members formed of first and second members arranged one after the other, and a plurality of vertically extending end members situated between two adjacent elongated members for connecting the same, said tortuous section extending in a spiral form to form a cylindrical shape with a first diameter so that locations of the end members gradually change from one

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side to the other side of the cylindrical shape along a central axis thereof, said first members extending substantially parallel to the central axis of the cylindrical shape, and

5 a plurality of joint members extending between two end members arranged in the cylindrical shape and situated adjacent to each other so that when a radial force is applied from an inside of the reinforcing member, the elongated members are bent relative to the end members to thereby allow the tubular reinforcing member to have a second diameter larger than the first diameter.

13. An expandable tubular reinforcing member according to claim 12, wherein said first and second members have sectional dimensions smaller at end portions than at middle portions to facilitate bending of the long and short members.

14. An expandable tubular reinforcing member according to claim 13, wherein said second members incline relative to the first members in a direction of expansion from the first diameter to the second diameter.

15. An expandable tubular reinforcing member according to claim 12, wherein the end members, which constitute parts of the tortuous section and face each other when the tortuous section is arranged in the cylindrical shape, are all connected together by the joint members extending spirally.

* * * * *

EXHIBIT M

US005824059A

United States Patent [19]

Wijay

[11] **Patent Number:** 5,824,059[45] **Date of Patent:** Oct. 20, 1998[54] **FLEXIBLE STENT**[76] **Inventor:** Bandula Wijay, 1903 Carriage Creek Dr., Friendswood, Tex. 77546[21] **Appl. No.:** 906,054[22] **Filed:** Aug. 5, 1997[51] **Int. Cl.⁶** A61F 2/06[52] **U.S. Cl.** 623/1[58] **Field of Search** 623/1, 11, 12;
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Primary Examiner—Michael J. Milano*Attorney, Agent, or Firm*—Rosenblatt & Redano, P.C.[57] **ABSTRACT**

A flexible stent is disclosed that can be constructed in a variety of ways. It can be made from a continuous wire formed into discrete rings of undulating bends where the end rings are closed up on themselves, and the continuous wire which forms the rings between the end rings defines longitudinal gaps in each of the internal rings, which gaps are in turn straddled by crossties which, in the preferred embodiment, extend in a perpendicular plane to the longitudinal axis of the stent, while being disposed in alignment with the cylindrical surface defined by the stent. The crossties act to keep the opening in the inner rings constrained during expansion of the stent. The presence of the longitudinal openings in the internal rings adds to the flexibility of the stent to ease delivery to the desired location. Alternatively, the flexible stent can be etched from a tube. In this preferred embodiment, alternating rings of an undulating wire-type element, etched from a tube, are presented. The rings alternate between those that are fully closed upon themselves, interspersed adjacent those that have a longitudinal opening, coupled by crossties which extend symmetrically from opposite sides and opposite ends of the longitudinal opening in the open rings to attach to the ring above and ring below. The disposition of the crossties helps the stent expand by providing resistance to opening of the longitudinal gap during expansion. The presence of the longitudinal gap adds to the flexibility of the stent for proper delivery to the desired location.

20 Claims, 2 Drawing Sheets

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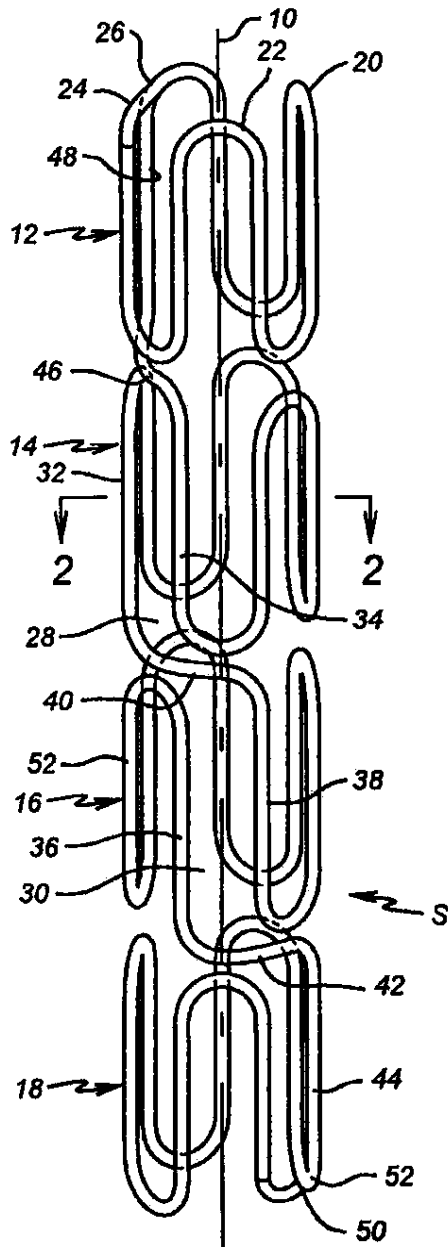


FIG. 1

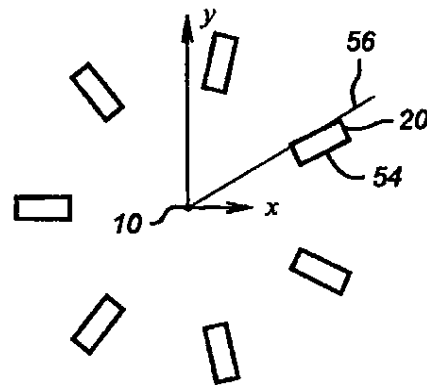


FIG. 2

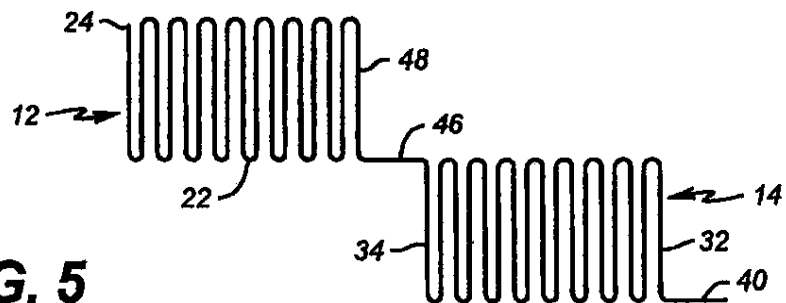


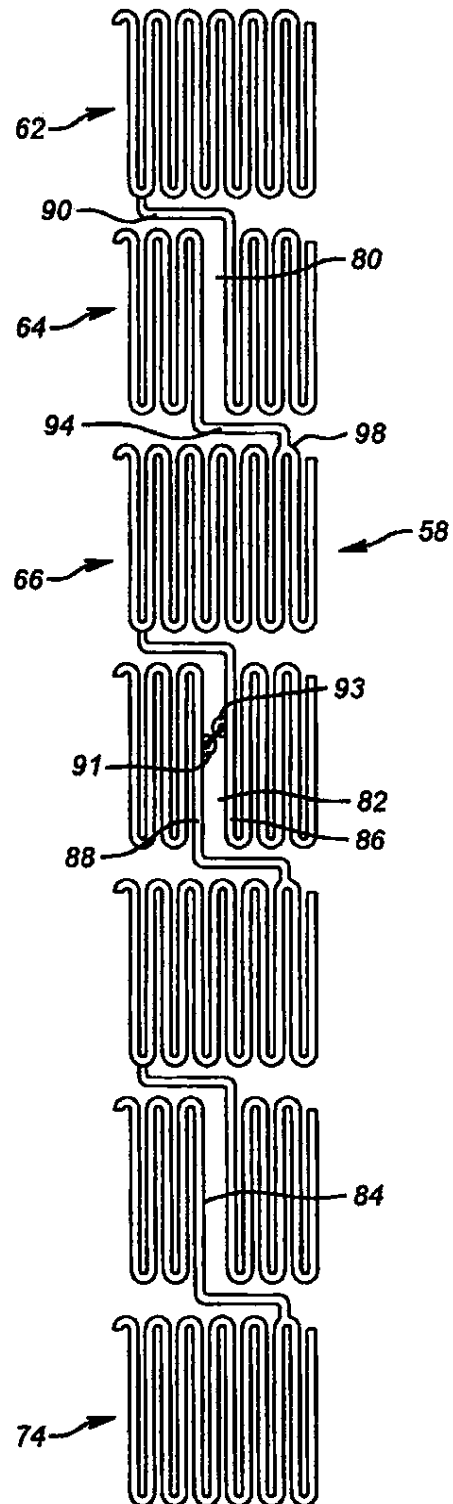
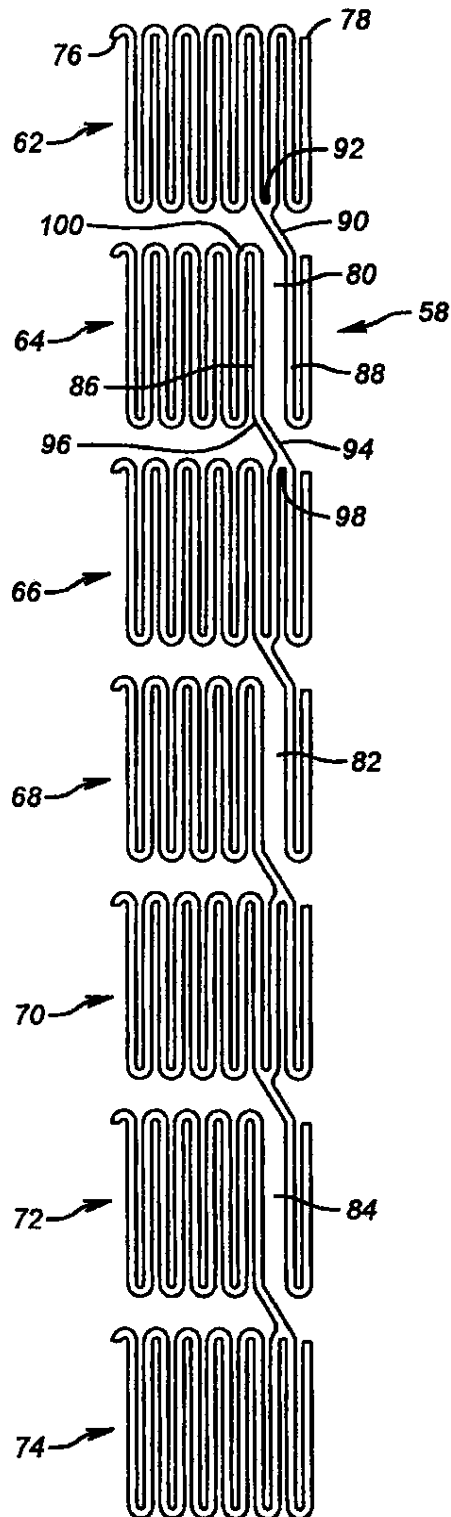
FIG. 5

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FLEXIBLE STENT

FIELD OF THE INVENTION

The field of this invention relates to vascular stents that can be delivered to a predetermined position and allowed to spring outwardly or, in the alternative, which can be expanded in place.

BACKGROUND OF THE INVENTION

Vascular stents are structures that are designed to maintain the patency of a vessel in the body. The stent provides internal support to allow the circulation to proceed there-through. Stents can be used in the vascular system in ureters, bile ducts, esophagus, and in many other tubular structures in the human body.

Stents can be tubular or can be made from wire. Stents are typically made from a metal or polymeric substance or a metal coated with polymers which are biocompatible or contain heparin to reduce blood clotting or other tissue reactions. Many prior designs have used a coil approach where a wire is helically wound on a mandrel. Yet other designs have evolved—braided wire mesh and angulated wire forms wrapped on a spindle to form a coil.

U.S. Pat. No. 5,292,331 by Boneau and U.S. Pat. No. 5,403,341 describe such wire forms. These devices have very poor radial support to withstand the hoop strengths of the artery or vein and further are not suitable for arteries that are bent or curved or for long lesions; multiple stents are required. These designs do not provide any support to hold the wall of the artery, other than the memory of the metal.

Wall Stent, produced by Pfizer Inc., is a braided wire tube. Although this stent is flexible so as to be placed in curved arteries or veins and other body cavities, it does not have any radial strength imparted to it by design.

Wiktor, U.S. Pat. Nos. 4,649,922; 4,886,062; 4,969,458; and 5,133,732 describe a wire form stent. He describes stents made of wire helix made of a preformed wire which is in the sinusoidal form, in which either all or some of the adjacent strands are connected.

Arthus Fontaine, U.S. Pat. No. 5,370,683, also describes a similar device where a flat wire form of sinusoidal shape is wound on a mandrel to form a helical coil. the wire bends are "U" shaped and are connected to alternate "U"-shaped bands.

Allen Tower, U.S. Pat. Nos. 5,217,483 and 5,389,106 describes a similar device where the wire is preformed to a sinusoidal shape and subsequently wound on a mandrel to form a helical coil.

All of the above-described art fails to provide radial support. The preshaped wire form (sinusoidal in most of the prior art) is wrapped on a mandrel to form a coil. However, the forces imported by the vessel wall's hoop strength are radially inward. In other words, the force is acting perpendicular to the plane of the U-shaped wire form. This means that the bends that are in the wire add no structural strength to the wire form to support the force produced by the wall, which is radially inward.

When we examine the simple coils, such as taught in U.S. Pat. Nos. Scott 5,383,928 or Gene Samson 5,370,691 or Rolando Gills 5,222,969, it is apparent that the spring coil will withstand substantial radial forces due to the vessel wall; however, all these stents are bulky in their pre-expanded form and are hard to place in small and curved arteries or veins of the body. Also, a major disadvantage of this design is that when the coil stent is placed in a curved

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artery or vein, it forms an "accordion" shape whereby some strands in the outer radius are spread and those of the inner radius are gathered. Spring coils can also "flip" to form a flat structure when a longitudinal force is applied on one side of the stent.

The other types of stents that have been developed are tube stents. Palmer, U.S. Pat. Nos. 4,733,665; 4,739,762; 7,776,337; and 4,793,348 describe such a tube stent of slotted metal tube. The slotted metal tube is expanded by a high-pressure balloon to implant the stent into the inside wall of the artery or vein.

Joseph Weinstein, U.S. Pat. No. 5,213,561 describes a similar stent made of tubular materials with slots cut into it. On expansion using a balloon, it forms a structure with diamond-shaped slots.

Henry Wall, U.S. Pat. No. 5,266,073 also describes a stent, tubular, that has slots machined into it. When expanded, the edges of the stent lock to form a cylinder. Not only is this device stiff and can only be used for short lesions, but also the diameter cannot be adjusted to meet the exact needs of the particular vessel but it is fixed to the predetermined sizes.

Lau and Hastigan, U.S. Pat. No. 5,344,426 describes a slotted tubular stent that has a structure similar to Henry Wall's but has provided prongs that will lock in as the stent is expanded.

Michael Marin, U.S. Pat. No. 5,397,355 also describes a tubular slotted stent with locking prongs.

U.S. Pat. No. 5,443,500 illustrates the use of square openings with rectangular prongs that stick therethrough to lock the stent. This design, as well as other locking mechanisms, generally have resulted in very stiff stents because of the use of a tubular-type grid construction. Further, the locking devices have resulted in sharp outwardly oriented tabs which are used for the locking, which could cause vascular damage.

All the above-described tube stents, although typically providing substantial radial support when expanded, are not flexible enough to be placed in curved vessels. Arteries and veins in the human body are mostly curved and are tapered. As such, these tube stents suffer from this main disadvantage.

European patent document 042172982 employs wires that are doubled up and whose ends are snipped off to make a given joint. Such doubling up at the junction of two elements with snipped off free ends creates a potential problem upon radial expansion. The sheer bulk of the doubled up wires makes them rotate radially outwardly away from the longitudinal centerline of the stent, while the plain ends on such an arrangement which are snipped off offer the potential of sharp points which can puncture or damage the intima. On the other hand, the apparatus of the present invention, employing sharp angles, as defined, avoids this problem in an embodiment which illustrates a continuous wire or wire-like member bent into a sharp angle. This type of structure alleviates the concerns of sharp edges, as well as the tendency of a doubled up heavy joint to rotate outwardly toward the intima upon radial expansion of the stem, as would be expected in the EPO reference 042172982.

Often these stents are layered with polymeric sheaths that are impregnated with biocompatible substances or can be coated with heparin or hydrogel. Most sheath-type coatings reduce endothelial cell growth through the stent, which is a major requirement in successful stenting of body cavities such as arteries and veins.

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Several parameters in design of stents are important. Of the more important parameters is the issue of recoil. Recoil deals with the memory of the stent material which, generally speaking, upon expansion in the blood vessel will want to recoil back to its original shape. This can be problematic because it is desirable for the stent, once expanded, to remain in good contact with the vessel wall to avoid longitudinal shifting. Furthermore, any recoil constricts the flow passage and presents a greater portion of the stent in the blood flowpath, thus creating additional complications due to the turbulence which ensues.

Related to the concern regarding recoil is another concern regarding component twist. This phenomenon generally occurs when the cross-sectional area of the components is rectangular, such as when the stent is manufactured from a cylindrical piece which is then cut by lasers or other means to form the particular pattern. Particularly in the honey-combed designs involving the use of square or rectangular element cross-sections, radial expansion of such stents generally results in a twist of the component segments such that they extend into the flowpath in the artery or vein. Again, this causes turbulence which is undesirable.

Related to the problem of recoil or constriction after expansion is the ability of the stent to anchor itself in the vascular wall. An anchoring system that does not cause trauma is a desirable feature not found in the prior art.

Yet other considerations which are desirable in a stent not found in the prior art is the flexibility to be maneuvered around bends in the vascular system, coupled with the ability to conform to a bend without kinking or leaving large open areas. The stents of the present invention have the objective of addressing the issue of recoil, as well as providing an anchoring mechanism to fixate the stent once set. Several of the designs incorporate flexibility to allow the stent to follow a bend or curve in a vascular flowpath while at the same time providing sufficient radial deformation to ensure proper fixation while minimizing angular twisting movements of the stent components to minimize turbulence through the stent.

In a recent article appearing in late 1995, by Dr. Donald S. Baim, entitled "New Stent Designs," a description is given of the ideal endovascular prosthesis. There, Dr. Baim indicates that the ideal stent should have low implantation profile with enhanced flexibility to facilitate delivery. He goes on to say that the stent should be constructed from a noncorrosive, nonthrombogenic radiopaque alloy and have expanded geometry which maximizes radial strength to resist vascular recoil. The ideal stent described by Baim is further described as having a wide range of diameters and lengths. Dr. Baim concludes that it is unlikely that any current designs satisfy all these requirements. Thus, one of the objectives of the present invention is to go further than the prior designs in satisfying the criteria for the ideal designs as set forth by Dr. Baim in his recent article.

SUMMARY OF THE INVENTION

A flexible stent is disclosed that can be constructed in a variety of ways. It can be made from a continuous wire formed into discrete rings of undulating bends where the end rings are closed up on themselves, and the continuous wire which forms the rings between the end rings defines longitudinal gaps in each of the internal rings, which gaps are in turn straddled by crossties which, in the preferred embodiment, extend in a perpendicular plane to the longitudinal axis of the stent, while being disposed in alignment with the cylindrical surface defined by the stent. The

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crossties act to keep the opening in the inner rings constrained during expansion of the stent. The presence of the longitudinal openings in the internal rings adds to the flexibility of the stent to ease delivery to the desired location. Alternatively, the flexible stent can be etched from a tube. In this preferred embodiment, alternating rings of an undulating wire-type element, etched from a tube, are presented. The rings alternate between those that are fully closed upon themselves, interspersed adjacent those that have a longitudinal opening, coupled by crossties which extend symmetrically from opposite sides and opposite ends of the longitudinal opening in the open rings to attach to the ring above and ring below. The disposition of the crossties helps the stent expand by providing resistance to opening of the longitudinal gap during expansion. The presence of the longitudinal gap adds to the flexibility of the stent for proper delivery to the desired location.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of one embodiment of the stent made from bent wire.

FIG. 2 is a sectional view along lines 2—2 of FIG. 1.

FIG. 3 is a flattened view of an alternative embodiment, illustrating alternating closed and open rings, with diagonally oriented crossties.

FIG. 4 is the design shown in FIG. 3, with a different arrangement for the crossties.

FIG. 5 is a flattened view of the stent shown in FIG. 1, showing a portion of the stent prior to its being wrapped on a mandrel.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

A first embodiment of the stent S of the present invention is shown in FIGS. 1 and 5. In FIG. 1, the stent is assembled into a tubular shape, having a longitudinal axis 10. Wrapped around the longitudinal axis 10 is a series of rings 12, 14, 16, and 18. Generally, rings 12 and 18 will be referred to as the end rings. Those skilled in the art will appreciate that varying amounts of intermediate rings, such as 14 and 16, can be used without departing from the spirit of the invention.

A continuous wire member 20, having any desired cross-sectional shape, is bent into an undulating pattern made up by a series of generally U-shaped segments 22. The end 24 of ring 12 is brought around and attached at point 26 to one of the U-shaped segments on ring 12 so as to close off ring 12 from having any longitudinal gaps. This is to be distinguished from the intermediate rings, such as 14 and 16, which each have a longitudinal gap 28 and 30, respectively. To better see the gaps in rings 14 and 16, the gap 28 is defined between segments 32 and 34, while the gap 30 is defined between segments 36 and 38. Referring to FIG. 1, it can be seen that segment 32 is ultimately connected to segment 38 via crosstie 40. Crosstie 40 preferably runs circumferentially following the cylindrical outer shape of rings 14 and 16 but disposed in between them such that crosstie 40, when viewed in the direction of cross-section lines 2—2, has a generally arcuate shape following the tubular shape of the stent S in a perpendicular plane to the longitudinal axis 10. At the lower end of the gap 30 is another crosstie 42, which forms as an extension of segment 36. Ultimately, crosstie 42 becomes segment 44 in end ring 18. With regard to opening 28, a crosstie 46 is an extension of segment 34 and finally extends and becomes segment 48 of end ring 12.

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In the preferred embodiment, the crossties follow the outer contours of the stent S, thus they have an arcuate shape. Pairs of crossties extend from opposed ends of a given opening. For example, with regard to longitudinal opening 30, crosstie 40, upon expansion of the stent S with a device such as a balloon, will pull in a clockwise direction on segment 38, while crosstie 42 will pull in a counterclockwise direction on segment 36. These opposing pulls from opposite sides of the gap 30 tend to hold the gap 30 from increasing significantly in size during expansion with a balloon. As a result, the undulating segments of ring 16, upon expansion of the stent S with a balloon or other device, will expand for setting the stent without appreciable increase in width of opening 30. However, the presence of opening 30, or opening 28 in ring 14, or any other longitudinal opening in an interior ring to the stent S, is to allow the stent to have greater flexibility during insertion. The longitudinal openings in the intermediate rings, such as 14 and 16, can be located on the stent S in longitudinal alignment or they can be offset, as shown in FIG. 1.

In the preferred embodiment, the end rings 12 and 14 do not have loose ends but rather have the end of the wire which forms the stent S rejoined to one of the undulating bends in that ring. Accordingly, the lower end ring 18 has an end 50, which is reconnected to a reversing U-type bend 52. It should be noted that while U-type undulating bends have been described in FIG. 1, different configurations for the individual rings, such as 12, 14, 16, and 18, can be employed without departing from the spirit of the invention. The undulating bends, such as 22, can comprise of segments that approach each other and come to a point or meet in some other fashion. The individual rings can also have diamond shapes. The significant feature of the stent is that the end rings close on themselves but retain a generally flexible structure to facilitate fixation by radial expansion, while the intermediate rings have a longitudinal opening characterized by crossties which create opposing forces on the opening to resist enlargement of the longitudinal opening upon radial expansion of the stent S when placed in position. In the preferred embodiment, the crossties have arcuate shapes and follow the profile of the stent S between adjacent rings, such as 14 and 16, such that they present opposing clockwise and counterclockwise forces from opposed ends of the opening to resist enlargement of the opening or gap while a given ring expands.

Thus, the preferred structure is illustrated, for example, by looking at longitudinal opening or gap 30 in ring 16, which is held against expansion when the stent is expanded by virtue of crossties 40 and 42. Crosstie 40 is on one side and one end of the longitudinal opening 30 and exerts a clockwise force, while crosstie 42 is on the opposite side and opposite end of opening 30 and exerts a counterclockwise force. The combination of the forces exerted by crossties 40 and 42 in opposed directions along the profile of the stent S helps to keep the opening 30 from significantly enlarging as the distance between other segments of ring 16, which form undulating bends, expand when the stent S is set. Thus, for example, in ring 16, the distance between segment 36 and segment 52 will increase as measured circumferentially when the stent S is expanded to a significant degree beyond any change to the circumferential distance between segments 36 and 38 which define the longitudinal gap 30.

FIG. 5 illustrates how the stent of FIG. 1 can be produced. It is understood that FIG. 5 is only a partial rendition of the stent shown in FIG. 1. Referring to FIG. 5, end 24 is illustrated for ring 12. Crosstie 46 presents the transition from segment 48, which is the last segment in ring 12, and

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segment 34, which is the first segment in ring 14. Thus, when the wire structure of FIG. 5 is rolled around a mandrel (not shown), the longitudinal opening 28 in ring 14 will be defined between segments 32 and 34, as shown in FIG. 1. FIG. 5 also shows crosstie 40, which becomes an extension of segment 32. By controlling the size of the reversing bends 22 and the length of the crosstie 46, the longitudinal gaps, such as 28 and 30, can be disposed in a circumferentially offset manner as shown in FIG. 1 or in a different pattern, such as in alignment with each other.

The cross-section of the wire material 20 can be round; however, other cross-sectional shapes can be used. To the extent an unsymmetrical cross-sectional shape is used for the wire 20, such as a rectangle, FIG. 2 illustrates a preferred orientation for the rectangular cross-section. FIG. 2 is a section view along lines 2—2 of FIG. 1 and illustrates the longitudinal axis 10 with the cross-sections of the wire having their longer sides 54 in alignment with a radius 56 extending from the longitudinal axis 10. By orienting the wire so that its long side 54 is in alignment with a radial line 56, additional benefits are obtained. The stent is made easier to flex radially such as when expanded by a balloon. This improves the results from use of the stent so that it is securely implanted. Additionally, orientation of the long dimension of the wire 20, in alignment with a radial line 56, facilitates the advancement of the stent to the position where it is to be deployed. As shown in FIG. 2, the stent S can flex more easily along the X and Y directions while it is being advanced with the long sides 54 in alignment with a radial line, such as 56.

It is also within the scope of the invention to include one or more closed intermediate rings in the design of FIG. 1.

While the stent shown in FIGS. 1 and 5 can be preferably fabricated from bending a wire, the stent shown in FIGS. 3 and 4 is amenable to being etched from a tube by known techniques. In the preferred embodiment of the invention as shown in FIG. 3, the stent 58 is shown in flattened form. It has a series of rings 62, 64, 66, 68, 70, 72, and 74. Those skilled in the art can appreciate that it can have any number of rings depending on the application, which is different than the number illustrated in FIG. 3 without departing from the spirit of the invention. Since the drawing in FIG. 3 is in flattened form, those skilled in the art will appreciate that end point 76 is, in fact, not an end point but is joined to what is shown as end point 78 (which is also not an end point when the tube is etched to make a three-dimensional stent on a mandrel). In essence, when the stent is made, what are shown in the drawing as end points 76 and 78 are not, in fact, end points but a continuation of the ring structure that makes up ring 62. In similar respects, the other rings illustrated in FIG. 3 are, in fact, unitary. What can readily be seen by examining FIG. 3 is that the end rings 62 and 74 have no longitudinal openings or gaps, while the interspersed rings 64, 68, and 72 each, respectively, have longitudinal openings or gaps 80, 82, and 84. While the openings 80, 82, and 84 are in longitudinal alignment in FIG. 3, they can be circumferentially misaligned when the stent structure 58 is formed without departing from the spirit of the invention. In the design of FIG. 3, as a typical example, the longitudinal opening 80 is formed by segments 86 and 88. An extension of segment 88 is diagonal crosstie 90, which ultimately joins a circumferentially offset U-bend 92 in ring 62. At the opposite side and opposite end of longitudinal opening 80, segment 86 continues as crosstie 94, which is bent preferably at about 45° at point 96 so that it joins U-bend 98 at a location circumferentially offset from opening 80. Thus, in the embodiment of FIG. 3, the crossties 90 and 94 link to the

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ring above and below, respectively, but at a circumferentially offset point. As a result, crosstie 90, when the stent 58 is expanded, puts a clockwise force on segment 88, while crosstie 94, when the stent 85 is radially expanded, puts a counterclockwise force on segment 86. The net result of the crossties 90 and 94 is to apply a closing force to segments 86 and 88, which make up the longitudinal opening 80, so that there is a greater resistance to growth of the opening 80 than there is to the widening of an individual set of return bends, such as 100. In a similar manner, the longitudinal openings 82 and 84 are impacted by their crossties from above and below. As seen by comparing FIGS. 3 and 4, and angular disposition of the crossties, such as 90 and 94, can employ more severe angles, such as about 90° to longitudinal axis 10, such that the crossties are literally disposed between individual rings, such as 62 and 64, for example. In FIG. 4, the crossties 90 and 94 have a generally arcuate shape and follow the tubular profile of the stent 58. As shown in FIG. 4, the crosstie 94 spans three return bends on ring 66 before being joined at U-bend 98. Thus, the concepts in the designs of FIGS. 3 and 4 are similar, with the difference being that the crossties, typically such as 90 and 94, exert greater closing forces on the longitudinal gaps, such as typically 80, while the stent 58 is being radially expanded. Also, tabs 91 and 93 can be placed on the members 86 and 88, and can be joined using a crosstie, such as thread, string, or wire made of metal or plastic. Although shown in one location in FIG. 4, it can be in all locations where a gap or opening such as 82 is disclosed.

While alternating closed rings and rings with gaps are disclosed in FIGS. 3 and 4, different patterns can be employed without departing from the spirit of the invention. Thus, more than one closed ring can be adjacent to another closed ring and, likewise, adjacent rings can have longitudinal gaps. The preferred embodiment of the stent 58 is as shown in FIG. 4, where the end rings 62 and 74 are of an undulating wire-like material with U-bends and are closed, with an alternating pattern of intermediate rings which are closed and those which have longitudinal openings, in combination with crossties which extend from opposite sides and opposite ends of the longitudinal openings so as to create opposing closing forces on the longitudinal openings. This, in turn, allows the rings with the longitudinal openings to expand radially at similar rates to the end rings, such as 62 and 74, when the stent 58 is expanded. In essence, the U-bends, such as 98, grow larger to set the stent 58 while the crossties, such as 90 and 94, hold the longitudinal openings, such as 80, to a relatively stable dimension.

In the preferred embodiment of FIG. 4, the longitudinal openings, such as 80, 82, and 84, are in alignment. Offset arrangements of the longitudinal openings are also within the scope of the preferred embodiment. As with the design of FIG. 1, the presence of the longitudinal openings, such as 80, 82, and 84, gives the stent 58 flexibility along its length in a variety of planes so that it can traverse tortuous passages to arrive at the location where it is to be expanded. The thickness of the material, which is used as the initial tube for etching to create the shapes shown in FIGS. 3 and 4, determines whether the cross-sectional area is symmetrical or asymmetrical. If it is asymmetrical, it is preferred that the cross-section of the individual wire-like segments, such as 86 and 88, is disposed in the manner shown in FIG. 2, where the longer dimension, such as 54, is in alignment with one of the radial lines, such as 56.

Those skilled in the art will appreciate that what has been disclosed is a stent that has flexibility for insertion, as well as a design which allows reliable radial expansion of the

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stent when it is located in the desired position. Whether the stent is manufactured of a wire that is continuously bent, or etched from a cylinder using known techniques, the presence of the longitudinal openings provides the desired flexibility for insertion, while at the same time the crossties, and the manner in which they are disposed with regard to the longitudinal openings, provide sufficient resistance to hoop stresses so that the reversing bends of a given ring, which has the longitudinal opening, will preferentially expand for setting the stent while the dimensions of the longitudinal openings, which had heretofore provided flexibility for advancement of the stent, are held in a relatively stable relationship to each other.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing from the spirit of the invention.

I claim:

1. A flexible stent, comprising:

a plurality of rings forming a generally cylindrical shape about a longitudinal axis;

each said ring connected to an adjacent ring by a crosstie; at least one first ring being one of said rings and formed having a gap which extends generally in the direction of the longitudinal axis and having crossties which extend from opposing segments of said ring which define said gap, respectively, to a ring above and a ring below in a manner which resists enlargement of the gap as the ring which defines said gap is radially expanded.

2. The stent of claim 1, wherein:

said crossties on said first ring conform to the cylindrical shape defined by said rings, said first ring having a top and a bottom;

a first crosstie is connected near the top of said first ring on one side of the gap, and a second crosstie is connected to said first ring near its bottom and on the opposite side of said gap.

3. The stent of claim 2, wherein:

said first and second crossties are oriented angularly at about 45° to the longitudinal axis.

4. The stent of claim 2, wherein:

said first and second crossties are oriented at about 90° to said longitudinal axis.

5. The stent of claim 2, wherein:

said first and second crossties extending symmetrically with respect to said gap and in opposed directions.

6. The stent of claim 5, wherein:

the rings on either end of the stent are closed and at least one said first ring with a gap is disposed in between.

7. The stent of claim 6, wherein:

a plurality of intermediate rings between said rings on either end where at least some intermediate rings have a gap and some of said gaps are longitudinally aligned.

8. The stent of claim 6, wherein:

a plurality of intermediate rings between said rings on either end where at least some intermediate rings have a gap and some of said gaps are longitudinally misaligned.

9. The stent of claim 6, wherein:

said rings are disposed in a layout where at least some of the rings which are closed are juxtaposed with rings with gaps.

10. The stent of claim 9, wherein:

some of the gaps in the rings are misaligned.

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11. The stent of claim 9, wherein:
some of the gaps in the rings are aligned.
12. The stent of claim 6, wherein:
said rings are formed of a wire-like member, bent in an undulating pattern which defines said generally cylindrical shape, said undulations formed by segments which move away from each other as said rings are radially expanded to fixate the stent;
- said gap is defined by two such opposed segments of a given ring and said first and second crosspieces create opposed forces on the segments defining said gap to resist expansion of said gap as the segments forming the undulations of a given ring move away from each other when the stent is fixated.
13. The stent of claim 12, wherein:
said wire-like member has an asymmetrical cross-section having a long dimension which, when viewed in a plane perpendicular to the longitudinal axis, is generally aligned with a radial line extending from the longitudinal axis.
14. The stent of claim 6, wherein:
a plurality of intermediate rings between said rings on either end where each intermediate ring has a gap and some of said gaps are longitudinally misaligned.

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15. The stent of claim 6, wherein:
said rings are disposed in a pattern where rings which are closed alternate with rings with gaps.
16. The stent of claim 13, wherein:
a plurality of intermediate rings between said rings on either end where each intermediate ring has a gap and some of said gaps are longitudinally misaligned.
17. The stent of claim 13, wherein:
said rings are disposed in a pattern where rings which are closed alternate with rings with gaps.
18. The stent of claim 17, wherein:
some of the gaps in the rings are aligned.
19. The stent of claim 18, wherein:
said first and second crosspieces are oriented angularly at about 45° to the longitudinal axis.
20. The stent of claim 18, wherein:
said first and second crosspieces are oriented at about 90° to said longitudinal axis.

* * * * *

EXHIBIT N



US005836964A

United States Patent [19][11] **Patent Number:** 5,836,964**Richter et al.**[45] **Date of Patent:** Nov. 17, 1998[54] **STENT FABRICATION METHOD**

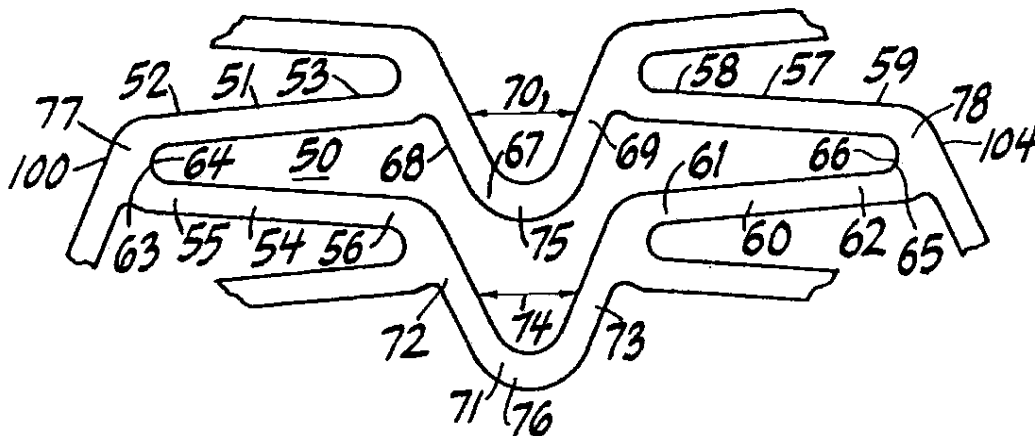
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[75] **Inventors:** Jacob Richter, Tel Aviv; Ira Yaron, Jerusalem, both of Israel*Primary Examiner*—Michael Powell Buiz*Assistant Examiner*—Kevin Truong[73] **Assignee:** Medinol Ltd., Tel Aviv, Israel*Attorney, Agent, or Firm*—Kenyon & Kenyon[21] **Appl. No.:** 742,422[57] **ABSTRACT**[22] **Filed:** Oct. 30, 1996[51] **Int. Cl.⁶** A61M 29/00[52] **U.S. Cl.** 606/194; 623/1; 606/198[58] **Field of Search** 606/194, 191, 606/198, 195, 192; 623/1, 12

A stent and a method for fabricating the stent are disclosed. The stent has an originally flat pattern and connection points where the sides of the flat pattern are joined. The method includes the steps of a) cutting a stent pattern into a flat piece of metal thereby to produce a metal pattern, b) deforming the metal pattern so as to cause two opposing sides to meet, and c) joining the two opposing sides at least at one point. Substantially no portion of the stent projects into the lumen of the stent when the stent is expanded against the internal wall of a blood vessel.

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21 Claims, 10 Drawing Sheets

U.S. Patent

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FIG. 1

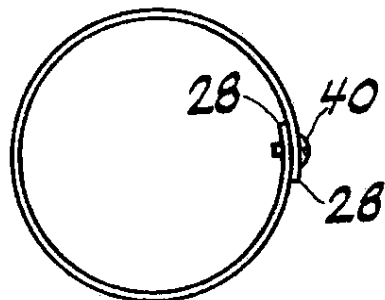
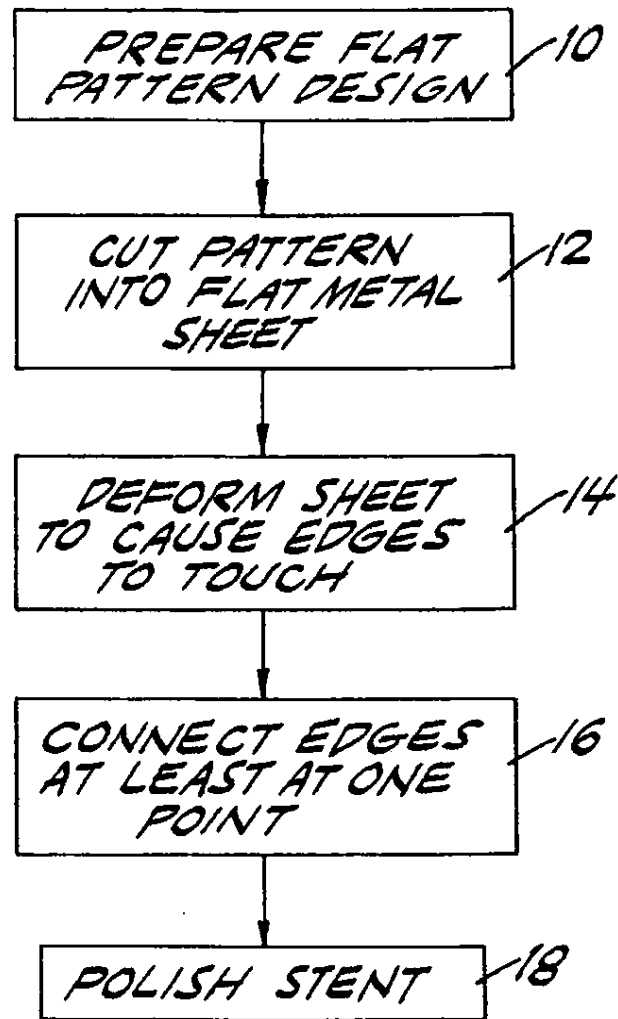


FIG. 6

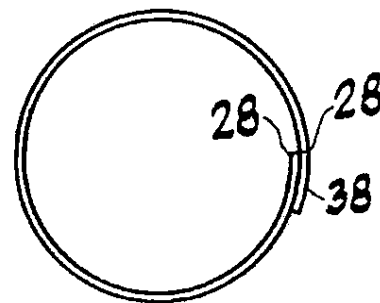


FIG. 5 A

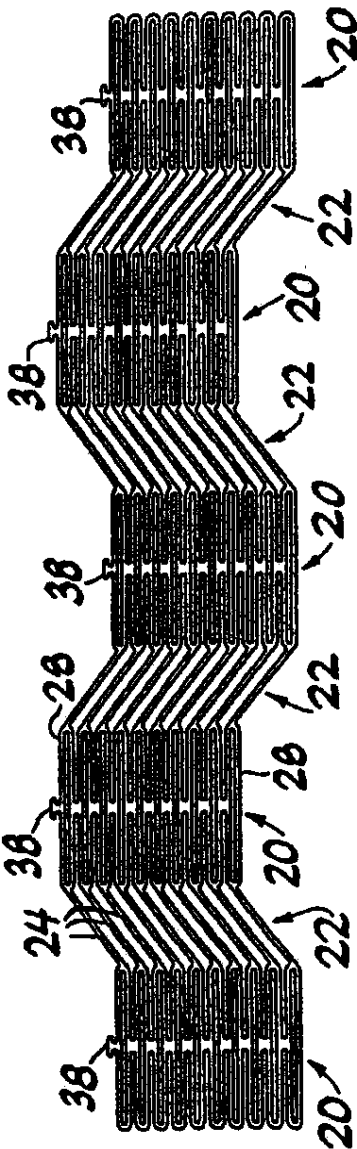


FIG. 2A

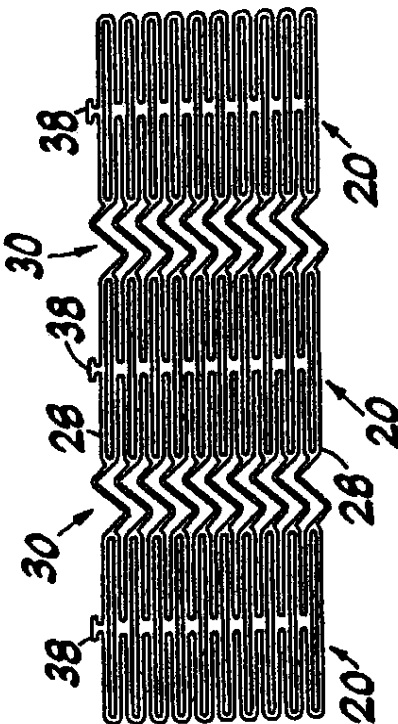


FIG. 2B

FIG. 2C

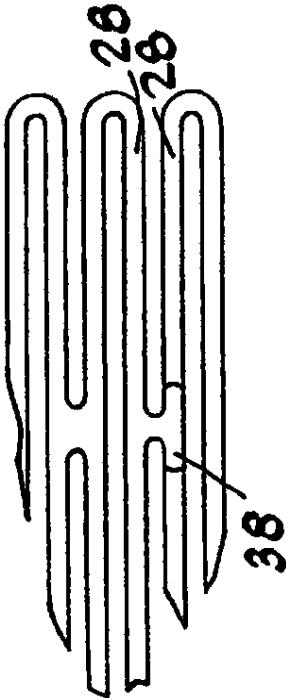
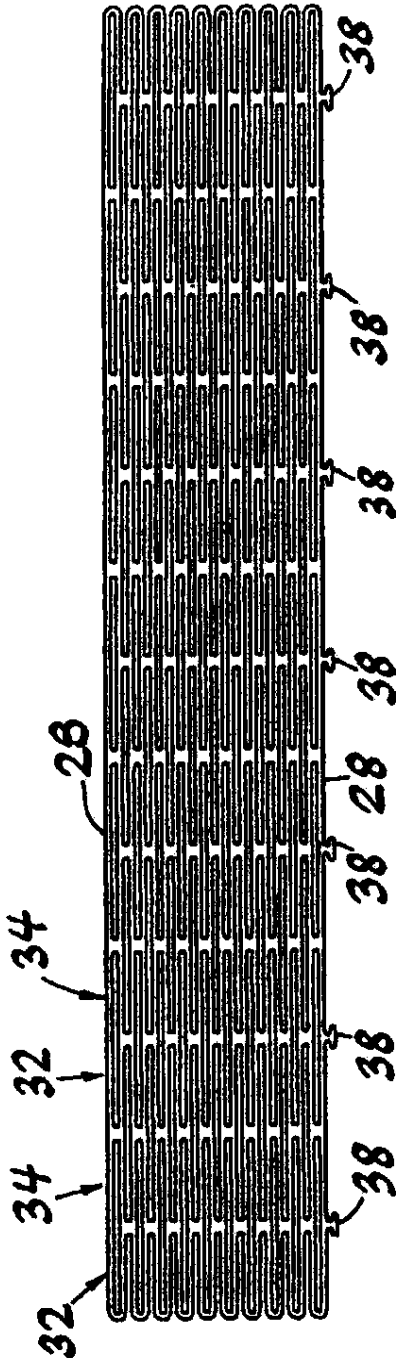


FIG. 5B

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FIG. 3

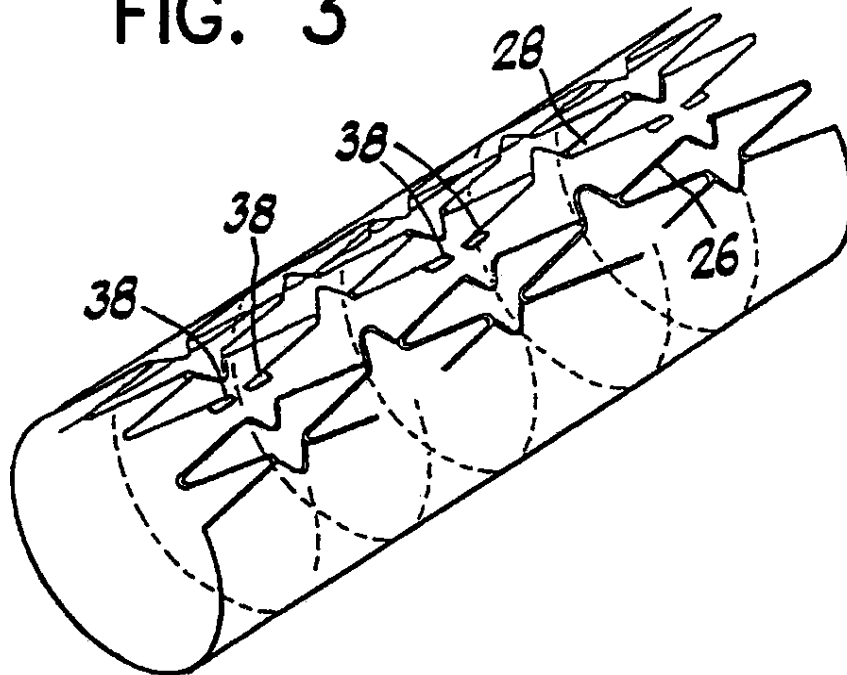
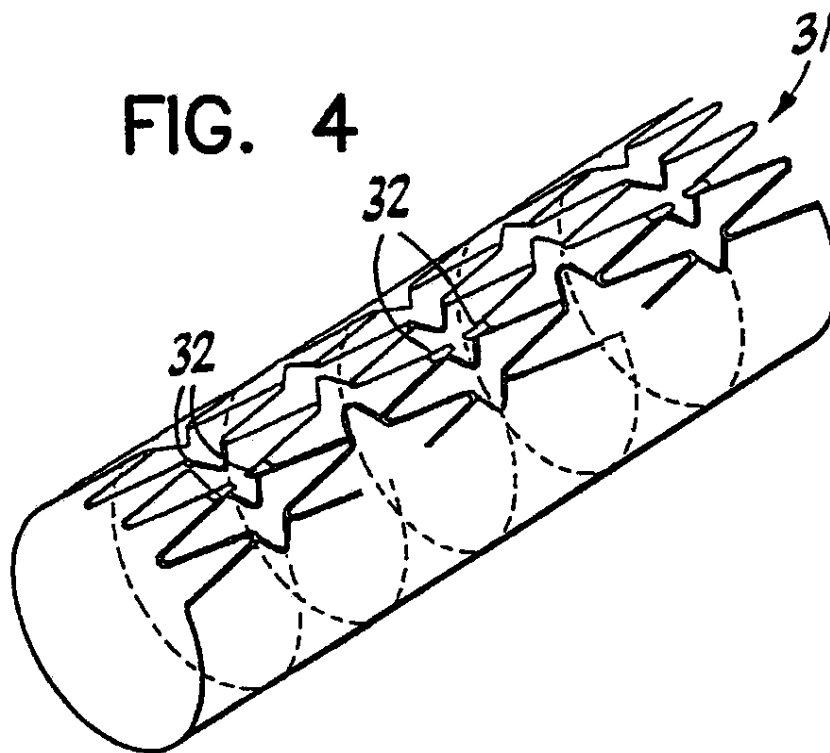
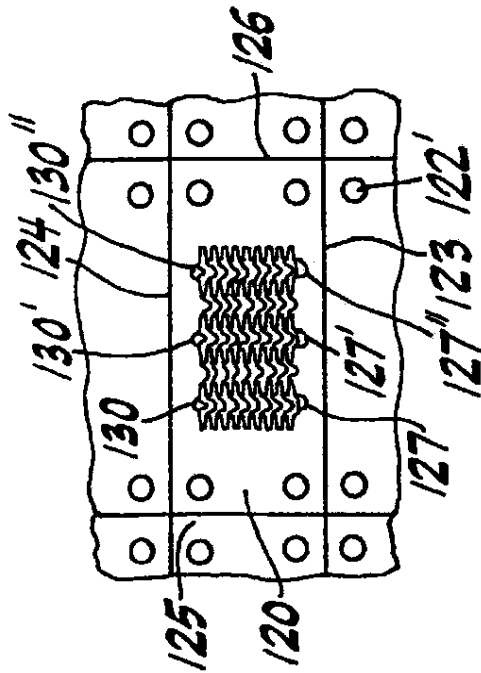


FIG. 4





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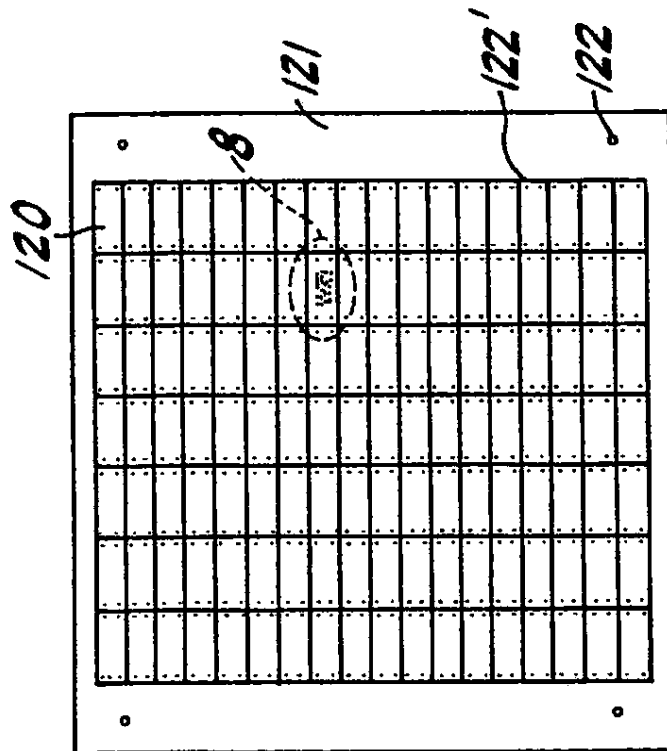


FIG. 7

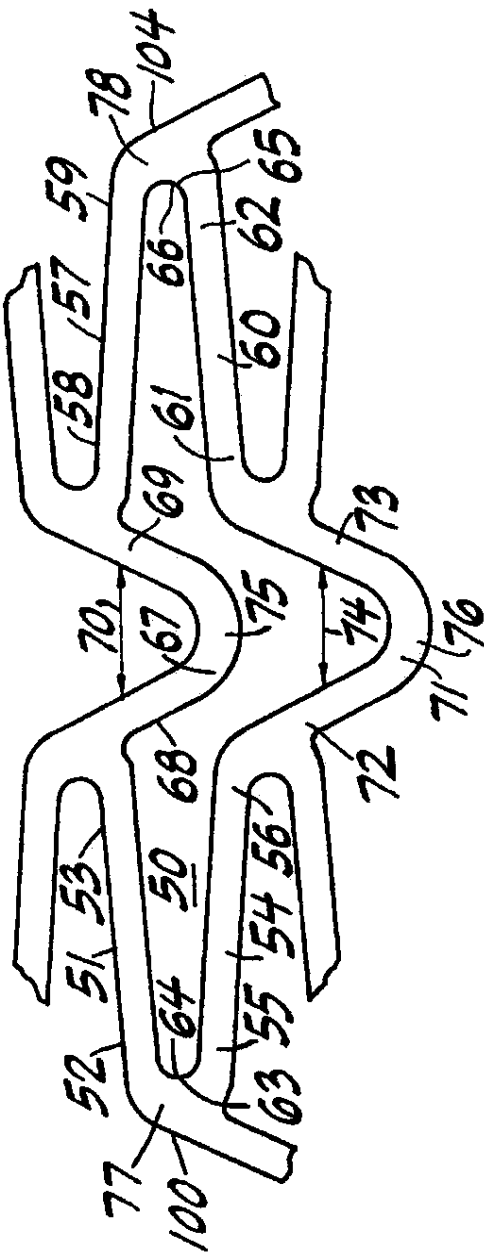


FIG. 14

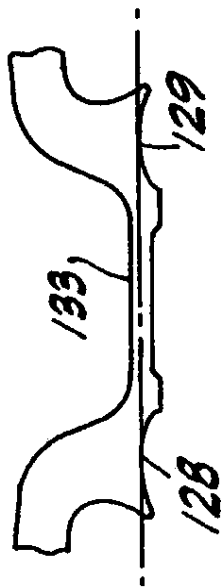


FIG. 9

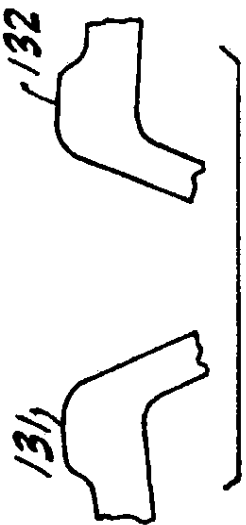


FIG. 10

FIG. 15

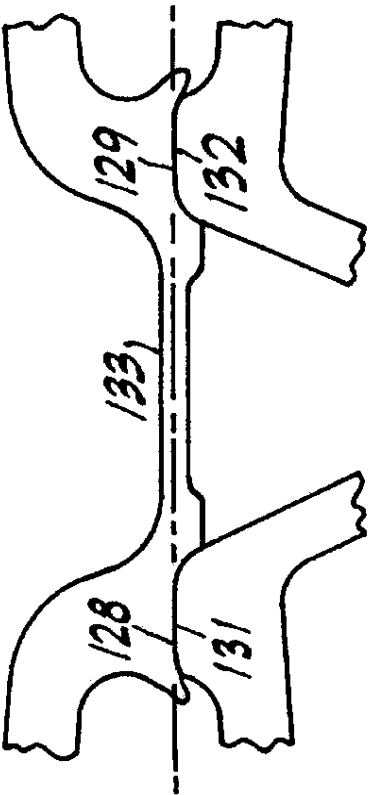
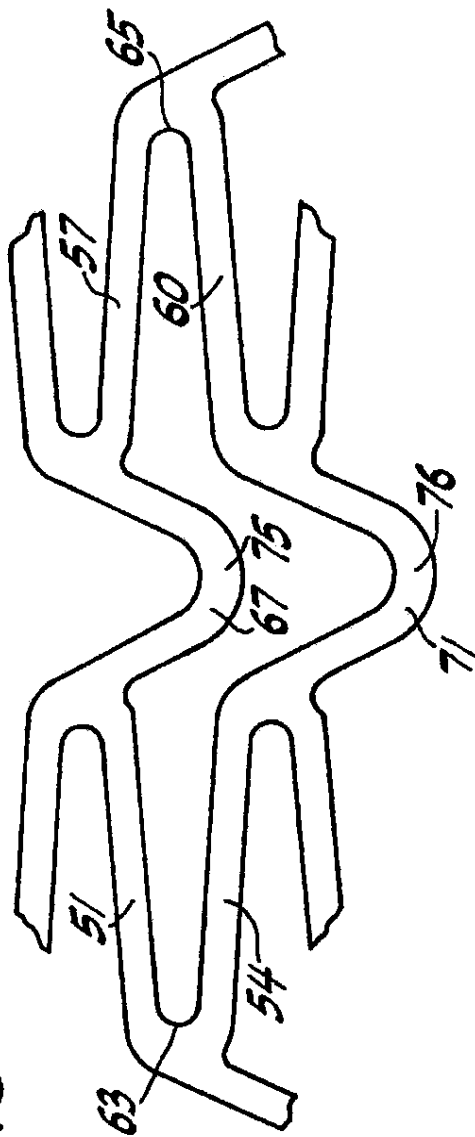


FIG. 11

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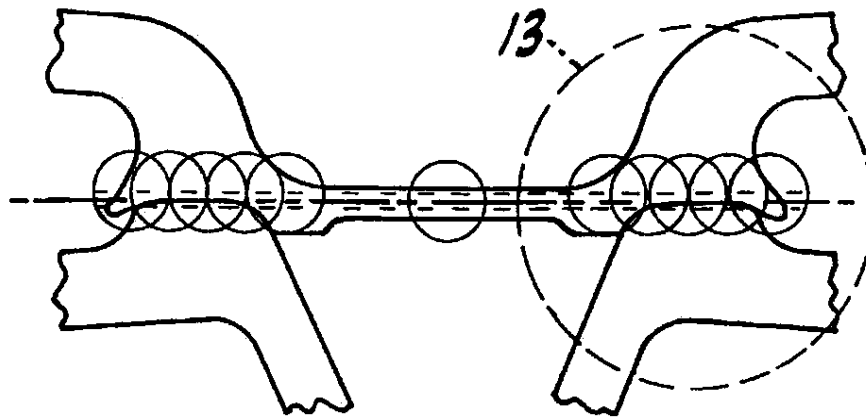


FIG. 12

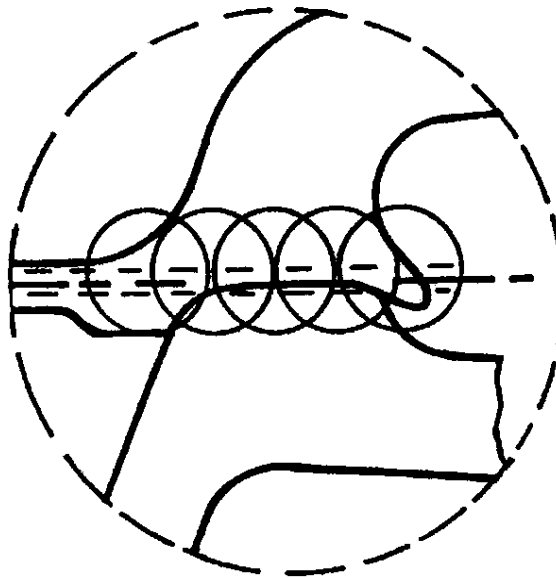


FIG. 13

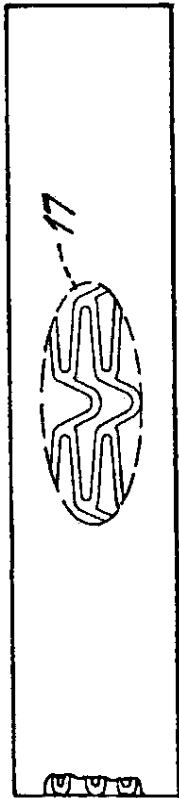


FIG. 16



FIG. 18

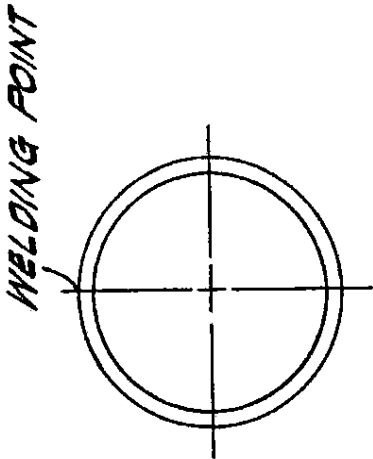


FIG. 19

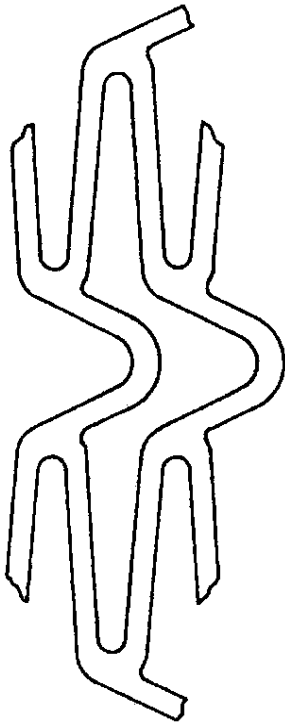


FIG. 17

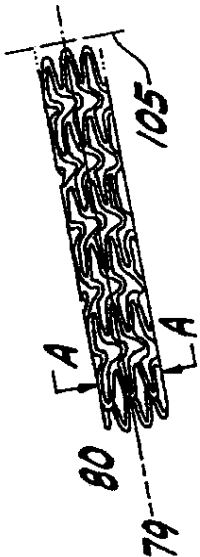


FIG. 20

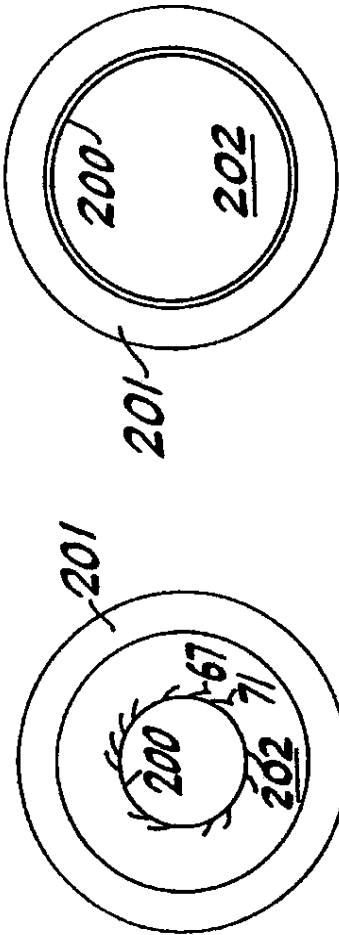


FIG. 21

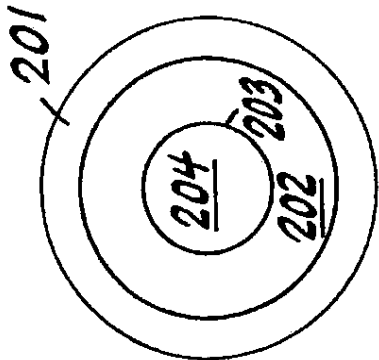


FIG. 23

FIG. 22

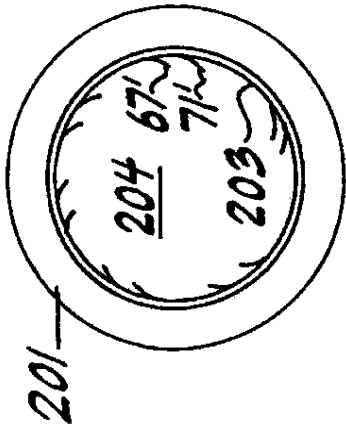


FIG. 24

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STENT FABRICATION METHOD**FIELD OF THE INVENTION**

The present invention relates generally to methods of fabricating stents.

BACKGROUND OF THE INVENTION

Stents are known in the art. They are typically formed of a cylindrical metal mesh which can expand when pressure is internally applied. Alternatively, they can be formed of wire wrapped into a cylindrical shape.

As described in U.S. Pat. No. 4,776,337 to Palmaz, the cylindrical metal mesh shape is produced by laser cutting a thin walled metal tube. The laser cuts away all but the lines and curves of the mesh.

The method of U.S. Pat. No. '337 is applicable for relatively large mesh shapes and for meshes whose lines are relatively wide. However, for more delicate and/or intricate shapes, the spot size of the laser is too large.

SUMMARY OF THE PRESENT INVENTION

It is, therefore, an object of the present invention to provide a stent fabrication method which can produce stents with relatively intricate and/or delicate designs.

The method involves first creating a flat version of the desired stent pattern from a piece of thin sheet metal. The flat pattern can be produced through any suitable technique, such as etching the design into the sheet metal, or by cutting with a very fine laser, should one become commercially available or by any other technique.

Once the sheet metal has been cut, it is deformed so as to cause its edges to meet. To create a cylindrical stent from a flat, roughly rectangular metal pattern, the flat metal is rolled until the edges meet. The locations where edges meet are joined together, such as by spot welding. Afterwards, the stent is polished, either mechanically or electrochemically.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

FIG. 1 is a flow chart illustration of the stent fabrication method of the present invention;

FIGS. 2A, 2B and 2C are illustrations of three alternative stent patterns to be etched, in accordance with the method of FIG. 1, into a flat sheet of metal;

FIG. 3 is an isometric illustration of a stent being deformed, useful in understanding the method of FIG. 1;

FIG. 4 is an isometric illustration of a stent formed from the method of FIG. 1;

FIGS. 5A and 5B are side and top view illustrations, respectively, of one connection location of the stent of FIG. 4;

FIG. 6 is a side view illustration of one connection location of the stent of FIG. 4 which is connected in a nail-like manner;

FIG. 7 shows a piece of sheet metal with a plurality of patterns made in accordance with the invention;

FIG. 8 shows a detailed view of one of the patterns shown in FIG. 7;

FIG. 9 shows a detailed view of a pair of engagement troughs shown in FIG. 8;

FIG. 10 shows a detailed view of a pair of engaging protrusions shown in FIG. 8;

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FIG. 11 shows the engagement troughs and engagement protrusions of FIGS. 9 and 10 in the engaged position;

FIG. 12 shows a welding run practiced in accordance with the invention;

FIG. 13 is a detailed view of the welding run shown in FIG. 12;

FIG. 14 is a detailed view of a cell of a stent made in accordance with this invention;

FIG. 15 is a detailed view of a cell made in accordance with this invention;

FIG. 16 shows a cell of a stent made in accordance with this invention;

FIG. 17 is an enlarged view of the cell shown in FIG. 16;

FIG. 18 is a cross-sectional view of a longitudinal member of a stent constructed in accordance with this invention;

FIG. 19 is a cross-sectional view of a stent constructed in accordance with this invention;

FIG. 20 is a perspective view of a stent constructed in accordance with this invention;

FIG. 21 is a cross-sectional front view of an unexpanded stent made in accordance with the invention;

FIG. 22 is a cross-sectional front view of the stent shown in FIG. 21 after it has been expanded;

FIG. 23 is a cross-sectional front view of an unexpanded stent made by cutting a pattern in a tube; and

FIG. 24 is a cross-sectional front view of the stent shown in FIG. 23 after expansion.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Reference is now made to FIG. 1, which illustrates the stent fabrication method of the present invention and to FIGS. 2A, 2B, 2C, 3 and 4 which are useful in understanding the method of FIG. 1.

In the stent fabrication method of the present invention, a stent designer first prepares a drawing of the desired stent pattern in a flat format (step 10).

FIGS. 2A, 2B and 2C illustrate three exemplary stent pattern designs. The pattern of FIG. 2A has two types of sections 20 and 22. Each section 20 has two opposing periodic patterns and each section 22 has a plurality of connecting lines 24. The pattern of FIG. 2A can be formed of any size; a preferable size is to have each section 20 be between 1 and 6 mm wide and each section 22 have connecting lines 24 of 1-6 mm long. At such sizes, the pattern of FIG. 2A cannot be cut using a laser cutting system.

The pattern of FIG. 2B is similar to that of FIG. 2A in that it also has sections 20 of opposing periodic patterns. The pattern of FIG. 2B also has connecting sections, labeled 30, which have a Z shape.

The pattern of FIG. 2C has no connecting sections. Instead, it has a series of alternating patterns, labeled 32 and 34.

The patterns of FIGS. 2A, 2B and 2C optionally also have a plurality of small protrusions 38 which are useful in forming the stent, as described hereinbelow.

Returning to FIG. 1, in step 12, the stent pattern is cut into a flat piece of metal ("sheet metal"). The metal can be any type of biocompatible material, such as stainless steel, or a material which is plated with a biocompatible material. The cutting operation can be implemented in any of a number of ways, such as by etching, or by cutting with a fine cutting tool, or by cutting with a very fine laser, should one become commercially available.

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If step 12 is implemented with etching, then, the process is designed to cut through the sheet metal. This process is known; however, for the purposes of completeness, it will be briefly described hereinbelow.

The drawing of the pattern is reduced and printed onto a transparent film. Since it is desired to cut completely through the metal, the drawing is printed onto two films which are joined together in a few places along their edges. The sheet metal is covered, on both sides, with a layer of photoresist and placed between the two transparent, printed films. The structure is illuminated on both sides which causes the portions of the photoresist which receive the light (which are all the empty spaces in the pattern, such as spaces 26 of FIG. 2A) to change properties.

The sheet metal is placed into acid which eats away those portions of the photoresist which changes properties. The sheet metal is then placed into an etching solution which etches away all material on which there is no photoresist-removing solution which removes the photoresist, leaving the metal having the desired stent pattern.

In step 14, the metal pattern is deformed so as to cause its long sides (labeled 28 in FIGS. 2A, 2B and 2C) to meet each other. FIG. 3 illustrates the deformation process. For cylindrical stents, the deformation process is a rolling process, as shown.

If the protrusions 38 have been produced, after deformation of the metal pattern, the protrusions 38 protrude over the edge 28 to which they are not attached. This is illustrated in FIG. 5A.

In step 16, the edges 28 are joined together by any suitable process, such as spot welding. If the protrusions 38 were made, the protrusions 38 are joined to the opposite edge 28, either by welding, adhesive or, as illustrated in FIG. 6, with a nail-like element 40. FIG. 5B illustrates the connection of the protrusion to the opposite edge 28. Since protrusion 38 is typically designed to extend the width of one loop 39, the pattern in approximately preserved. This is seen in FIG. 5B.

Alternatively, the edges 28 can be brought together and joined in the appropriate places.

FIG. 4 illustrates a stent 31 formed by the process of steps 10-16 for the pattern of FIG. 2A. It is noted that such a stent has connection points 32 formed by the joining of the points 30.

Finally, the stent 31 is polished to remove any excess material not properly removed by the cutting process (step 12). The polishing can be performed mechanically, by rubbing a polishing stick having diamond dust on its outside inside the stent 31. Alternatively, an electropolishing unit can be utilized.

FIG. 7 shows an alternative embodiment of the invention in which a plurality of patterns 120 are etched and cut into the sheet metal 121 as previously discussed. FIG. 8 is an enlarged view of one of the plurality of patterns 120 shown in FIG. 7.

FIG. 9 is an enlarged view of one pair 127 of the plurality of engagement troughs 128 and 129 shown in FIG. 8. FIG. 10 is an enlarged view of one pair 130 of the plurality of engagement protrusions 131 and 132 shown in FIG. 8. The sheet metal 121 and each of the patterns 120 is provided with a plurality of alignment apertures 122 and 122' adapted to receive sprockets (not shown) for precisely moving and maintaining the precise alignment of the sheet metal 121 and the patterns 120 during the various stages of manufacturing. Each pattern 120 has a first long side 123 and a second long side 124, a first short side 125, and a second short side 126.

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The first long side 123 is provided with a plurality of pairs 127, 127' and 127" of engagement troughs 128 and 129 (shown in greater detail in FIG. 9). Each pair 127, 127' and 127" of engagement troughs has a first engagement trough 128 and a second engagement trough 129. The second long side 124 is provided with a plurality of pairs 130, 130' and 130" of engagement protrusions (shown in greater detail in FIG. 10). Each pair 130, 130' and 130" of engagement protrusions is provided with a first engagement protrusion 131 and a second engagement protrusion 132. The pairs of engagement protrusions 130, 130' and 130" are disposed substantially opposite the pairs of engagement troughs 127, 127' and 127".

The engagement troughs 128 and 129 are disposed and adapted to receive and engage the engagement protrusions 131 and 132 so that the alignment of the stent is maintained when the pattern 120 is deformed and the flat sheet metal is rolled so that the first long side 123 and the second long side 124 meet each other to form a tube as shown in FIGS. 19 and 20.

A bridge 133 of material is disposed between each pair 127, 127' and 127" of engagement troughs 128 and 129. This bridge 133 imparts additional stability and facilitates alignment during manufacturing and imparts additional strength to the welds of the finished stent as discussed below.

After the sheet has been rolled into a tubular stent and the engagement troughs 128 and 129 have received the engagement protrusions 131 and 132, means (not shown) are utilized to maintain the alignment and the bridge 133 is cut to leave two substantially equal parts. The bridge 133 may be cut in a variety of ways well known to those skilled in the art, however, in a preferred embodiment, a laser is utilized. Engagement trough 128 is welded to engagement protrusion 131 and engagement trough 129 is welded to engagement protrusion 132 as shown in FIGS. 12 and 13. This may be accomplished in a variety of ways well known to those skilled in the art, however, in a preferred embodiment a plurality of spot welds are utilized. In an especially preferred embodiment, about five spot welds are used in each weld run as shown in FIGS. 12 and 13. The heat produced by the welding melts the cut bridge 133 material and the material is drawn towards the engagement trough 128 or 129 to which the material is attached and is drawn into the welded area between the engagement trough and the engagement protrusion where the additional bridge material becomes part of and imparts additional strength to the weld. The stent may then be finished as previously discussed.

FIG. 13 is an enlarged view of the welded area shown in FIG. 12. In a preferred embodiment, the weld run is offset from the point where the engagement trough and the engagement protrusion contact each other. In an especially preferred embodiment, the weld run is offset about 0.01 mm.

FIG. 14 is a detailed view of the pattern shown in FIG. 8. As shown in FIGS. 14 and 20, Applicants' invention can also be described as an expandable stent defining a longitudinal aperture 80 having a longitudinal axis or extension 79 and a circumferential axis or extension 105, including a plurality of flexible connected cells 50 with each of the flexible cells 50 having a first longitudinal end 77 and a second longitudinal end 78. Each cell 50 also is provided with a first longitudinal apex 100 disposed at the first longitudinal end 77 and a second longitudinal apex 104 disposed at the second longitudinal end 78. Each cell 50 also includes a first member 51 having a longitudinal component having a first end 52 and a second end 53; a second member 54 having a longitudinal component having a first end 55 and a second

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end 56; a third member 57 having a longitudinal component having a first end 58 and a second end 59; and a fourth member 60 having a longitudinal component having a first end 61 and a second end 62. The stent also includes a first loop 63 defining a first angle 64 disposed between the first end 52 of the first member 51 and the first end 55 of the second member 54. A second loop 65 defining a second angle 66 is disposed between the second end 59 of the third member 57 and the second end 62 of the fourth member 60 and is disposed generally opposite to the first loop 63. A first flexible compensating member or flexible link 67 having a first end 68 and a second end 69 is disposed between the first member 51 and the third member 57 with the first end 68 of the first flexible compensating member or flexible link 67 communicating with the second end 53 of the first member 51 and the second end 69 of the first flexible compensating member or flexible link 67 communicating with the first end 58 of the third member 57. The first end 68 and the second end 69 are disposed a variable longitudinal distance 70 from each other. A second flexible compensating member 71 having a first end 72 and a second end 73 is disposed between the second member 54 and the fourth member 60. The first end 72 of the second flexible compensating member or flexible link 71 communicates with the second end 56 of the second member 54 and the second end 73 of the second flexible compensating member or flexible link 71 communicates with the first end 61 of the fourth member 60. The first end 72 and the second end 73 are disposed a variable longitudinal distance 74 from each other. In a preferred embodiment, the first and second flexible compensating member or flexible links 67 and 71 are arcuate. The first and second flexible compensating member or flexible links 67 and 71 are differentially extendable or compressible when the stent is bent in a curved direction away from the longitudinal axis 79 of the aperture 80. (Shown in FIG. 20.) The first member 51, second member 54, third member 57, and fourth member 60 and the first loop 63 and the second loop 65 and the first flexible compensating member or flexible link 67 and the second flexible compensating member or flexible link 71 are disposed so that as the stent is expanded the distance between the first flexible compensating member or flexible link 67 and the second flexible compensating member or flexible link 71 increases and the longitudinal component of the first member 51, second member 54, third member 57 and fourth member 60 decreases while the first loop 63 and the second loop 65 remain generally opposite to one another, the ends 68 and 69 of the first flexible compensating member or flexible link 67 and the ends 72 and 73 of the second flexible compensating member or flexible link 71 open so as to increase the variable longitudinal distance 70 between the first end 68 and the second end 69 of the first flexible compensating member or flexible link 67 and so as to increase the variable longitudinal distance 74 between the first end 72 and the second end 73 of the second flexible compensating member or flexible link 71. This compensates for the decreasing of the longitudinal component of the first member 51, second member 54, third member 57, and fourth member 60 and substantially lessens the foreshortening of the stent upon its expansion. Upon expansion, the first flexible compensating member 67 and the second flexible compensating member 71 impart support to the lumen being treated.

FIG. 15 shows the dimensions of an especially preferred embodiment of this invention. The deflection points, i.e., the first and second loops 63 and 65 and the first and second compensating members 67 and 71, are made wider than the

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first, second, third, and fourth members 51, 54, 57 and 60 so that the force of the deflection is distributed over a wider area upon the expansion of the stent. The deflection points can be made wider than the first, second, third and fourth members in differing amounts so that the deflection will occur in the narrower areas first due to the decreased resistance. In a preferred embodiment, the first and second compensating members are wider than the first, second, third and fourth members and the first and second loops are wider than the first and second compensating members. One of the advantages of sizing the first and second loops so that they are wider than the first and second compensating members is that the stent will substantially compensate for foreshortening as the stent is expanded. In the embodiment shown in FIG. 15, the first, second, third and fourth members 51, 54, 57 and 60 have a width of about 0.1 mm. The first and second loops 63 and 65 have a width of about 0.14 mm. The first and second compensating members 67 and 71 are provided with a thickened portion 75 and 76 having a width of about 0.12 mm. Thus, in this especially preferred embodiment, the first and second loops have a width that is about 40% greater and the first and second compensating members have a width that is about 20% greater than the width of the first, second, third and fourth members.

FIGS. 16 through 20 show details of a stent constructed in accordance with this invention.

Yet another advantage of Applicant's invention is shown in FIGS. 21 to 24. For the sake of clarity, the dimensions and the degree of displacement of the components of the stents shown in FIGS. 21 to 24 has been intentionally exaggerated.

FIG. 21 is a cross-sectional front view taken along line A-A of the unexpanded stent made in accordance with applicant's invention shown in FIG. 20. The unexpanded stent 200 of FIG. 21 is shown disposed in the lumen 202 of a blood vessel 201 prior to expansion. As previously discussed, this stent is made by first cutting the stent pattern into a flat piece of sheet metal and then rolling the sheet metal into a tube to form the tubular stent. As shown in FIG. 21 after rolling, the first and second flexible compensating members 67 and 71 of the unexpanded stent tend to "flare out" in a direction away from the longitudinal axis or lumen of the stent. Thus, the flexible compensating members 67 and 71 define outer diameters which are larger than the outer diameters defined by the remaining portions of the stent. FIG. 22 shows the stent of FIG. 21 after it has been expanded in the lumen and against the internal wall of the blood vessel. As shown in FIG. 22, upon expansion of the unexpanded stent toward the wall of the blood vessels, the walls of the blood vessel imparts a mechanical force to the first and second flexible compensating members 67 and 71 and the compensating members move toward the longitudinal axis or lumen of the stent until they are substantially in registry with the remaining portion of the stent. Thus, the lumen of the expanded stent is substantially circular when viewed in cross section with substantially no portion of the expanded stent projecting into the lumen or towards the longitudinal axis of the expanded stent.

FIG. 23 is similar to FIG. 21 except that the pattern has been cut into a tubular member using conventional methods of making stents. As shown in FIG. 23, the flexible compensating members do not flare out away from the longitudinal axis of the unexpanded stent 203. Upon the expansion of the stent shown in FIG. 23 toward the walls of the blood vessel 201, the flexible compensating members 67' and 71' tend to "flare in" and project into the lumen 204 of the expanded stent 203.

FIG. 24 shows the stent 203 of FIG. 23 after it has been expanded in a lumen 204 of a blood vessel 201. The flexible

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compensating members 67 and 71 are not in registry with the remaining portions of the stent and define a diameter smaller than the diameter of remaining portions of the stent. These projections into the lumen of the stent create turbulence in a fluid flowing through the longitudinal axis of the expanded stent and could result in clot formation.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined only by the claims which follow.

We claim:

1. A sheet for fabricating a stent having a longitudinal lumen having a longitudinal axis comprising:

- a) a flat piece of metal provided with a plurality of stent patterns, each of said patterns comprising a plurality of flexible connected cells, each of said flexible cells comprising:
 - a) a first member having a longitudinal component having a first end and a second end;
 - b) a second member having a longitudinal component having a first end and a second end;
 - c) a third member having a longitudinal component having a first end and a second end;
 - d) a fourth member having a longitudinal component having a first end and a second end;
 - e) a first loop defining a first angle disposed between said first end of said member and said first end of said second member;
 - f) a second loop defining a second angle disposed between said second end of said third member and said second end of said fourth member, and disposed generally opposite to said first loop;
 - g) a first flexible compensating member having a first end and a second end disposed between said first member and said third member, said first end of said first flexible compensating member communicating with said second end of said first member and said second end of said first flexible compensating member communicating with said first end of said third member, said first and said second ends disposed a variable longitudinal distance from each other;
 - h) a second flexible compensating member having a first end and a second end disposed between said second member and said fourth member, said first end of said second flexible compensating member communicating with said first end of said fourth member, said first and said second ends disposed a variable longitudinal distance from each other, said first and said second flexible compensating member differentially expendable or compressible when said stent is bent in a curved direction away from said longitudinal axis of said lumen; and
 - i) said first, said second, said third, and said fourth members and said first and said second loops, and said first and said second flexible compensating members disposed so that as said stent is expanded the distance between said first and said second flexible compensating member increases and the longitudinal component of said first, second, third and fourth members decreases while said first and said second loops remain generally opposite to one another, the ends of said first and said second flexible compensating member open so as to increase said variable longitudinal distance between said first and said second ends of said first flexible compensating member and so as to increase said variable longitudinal distance between said first and said second

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ends of said second flexible compensating member so as to compensate for the decreasing of the longitudinal component of said first, second, third, and fourth members and substantially lessen the foreshortening of said stent upon its expansion;

each of said plurality of stent patterns having a first long side and a second long side, said first long side provided with a plurality of pairs of engagement troughs, said second long side provided with a plurality of pairs of engagement protrusions, said plurality of pairs of engagement troughs and said plurality of pairs of engagement protrusions disposed substantially opposite each other, each of said plurality of pairs of engagement troughs comprising a first engagement trough and a second engagement trough, said engagement troughs sized and disposed to receive and engage said engagement protrusions when said sheet is deformed and rolled into a tubular shape, each pair of said engagement troughs provided with a bridge disposed between said first engagement trough and said second engagement trough, wherein said first loop, said second loop, said first compensating member, and said second compensating member are wider than said first, second, third and fourth members.

2. The sheet of claim 1, further comprising a plurality of alignment apertures disposed in said flat metal sheet.

3. The sheet of claim 1, wherein said first and said second compensating members are wider than said first, second, third, and fourth members and said first and said second loops are wider than said first and said second compensating members.

4. The sheet of claim 3, wherein said first and said second loops have a width that is about 40% greater than the width of said first, second, third, and fourth members and said first and said second compensating members have a width that is about 20% greater than the width of said first, second, third, and fourth members.

5. An expandable stent having a longitudinal lumen comprising:

- a) a first long side and a second long side, said first long side provided with a plurality of pairs of engagement troughs, said second long side provided with a plurality of pairs of engagement protrusions, said plurality of pairs of engagement troughs and said plurality of pairs of engagement protrusions disposed substantially opposite each other, said plurality of engagement troughs sized and disposed to receive and engage said engagement protrusions, said engagement troughs attached to said engagement protrusions, wherein said engagement troughs are attached to said engagement protrusions by a weld.

6. The stent of claim 5, wherein said weld is offset from the point where said engagement troughs and said engagement protrusions contact each other.

7. The stent of claim 6, wherein said weld is offset about 0.01 mm from the point where said engagement troughs and said engagement protrusions contact each other.

8. The stent of claim 5, wherein said weld is a spot weld.

9. The stent of claim 8, wherein a plurality of spot welds is utilized.

10. The stent of claim 9, wherein 5 spot welds are utilized.

11. The stent of claim 5, wherein said engagement troughs are attached to said engagement protrusions by an adhesive.

12. The stent of claim 5, wherein said engagement troughs are attached to said engagement protrusions by a nail-like element.

13. An expandable stent having a longitudinal lumen having a longitudinal axis comprising:

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- a) a stent pattern comprising a plurality of flexible connected cells, each of said flexible cells comprising:
- a) a first member having a longitudinal component having a first end and a second end;
 - b) a second member having a longitudinal component having a first end and a second end;
 - c) a third member having a longitudinal component having a first end and a second end;
 - d) a fourth member having a longitudinal component having a first end and a second end;
 - e) a first loop defining a first angle disposed between said first end of said first member and said first end of said second member;
 - f) a second loop defining a second angle disposed between said second end of said third member and said second end of said fourth member, and disposed generally opposite to said first loop;
 - g) a first flexible compensating member having a first end and a second end disposed between said first member and said third member, said first end of said first flexible compensating member communicating with said second end of said first member and said second end of said first flexible compensating member communicating with said first end of said third member, said first and said second ends disposed a variable longitudinal distance from each other;
 - h) a second flexible compensating member having a first end and a second end disposed between said second member and said fourth member, said first end of said second flexible compensating member communicating with said first end of said fourth member, said first and said second ends disposed a variable longitudinal distance from each other, said first and said second flexible compensating member differentially expendable or compressible when said stent is bent in a curved direction away from said longitudinal axis of said lumen; and
 - i) said first, said second, said third, and said fourth members and said first and said second loops, and said first and said second flexible compensating member disposed so that as said stent is expanded the distance between said first and said second flexible compensating member increases and the longitudinal component of said first, second, third and fourth members decreases while said first and said second loops remain generally opposite to one another, the ends of said first and said second flexible compensating member open so as to increase said variable longitudinal distance between said first and said second ends of said first flexible compensating

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member and so as to increase said variable longitudinal distance between said first and said second ends of said second flexible compensating member so as to compensate for the decreasing of the longitudinal component of said first, second, third, and fourth members and substantially lessen the foreshortening of said stent upon its expansion;

said stent pattern having a first long side and a second long side, said first long side provided with a plurality of pairs of engagement troughs, said second long side provided with a plurality of pairs of engagement protrusions, said plurality of pairs of engagement protrusions and said plurality of pairs of engagement troughs disposed substantially opposite each other, each of said plurality of pairs of said engagement troughs comprising a first engagement trough and a second engagement trough, said engagement troughs attached to said engagement protrusions, wherein said first loop, said second loop, said first compensating member, and said second compensating member are wider than said first, second, third, and fourth members.

14. The stent of claim 13, wherein said first and said second compensating members are wider than said first, second, third, and fourth members and said first and said second loops are wider than said first and said second compensating members.

15. The stent of claim 14, wherein said first and said second loops have a width that is about 40% greater than the width of said first, second, third, and fourth members and said first and said second compensating members have a width that is about 20% greater than the width of said first, second, third, and fourth members.

16. The stent of claim 13, wherein said engagement protrusions are attached to said engagement troughs by a weld.

17. The stent of claim 16, wherein said weld is offset from the point where said engagement troughs and said engagement protrusions contact each other.

18. The stent of claim 17, wherein said weld is offset about 0.01 mm from the point where said engagement troughs and said engagement protrusions contact each other.

19. The stent of claim 16, wherein said weld is a spot weld.

20. The stent of claim 19, wherein a plurality of spot welds is utilized.

21. The stent of claim 20, wherein 5 spot welds are utilized.

* * * * *

EXHIBIT O

REDACTED

EXHIBIT P

REDACTED

EXHIBIT Q

REDACTED